



Healthcare Fraud and Abuse Review
2016

BASSBERRY  SIMS PLC

1.

A LOOK BACK...A LOOK AHEAD

4.

NOTEWORTHY SETTLEMENTS

7.

ISSUES TO WATCH

10.

FALSE CLAIMS ACT UPDATE

35.

STARK LAW/ANTI-KICKBACK STATUTE

38.

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

42.

APPENDIX - 2016 NOTABLE SETTLEMENTS

Hospitals and Hospital Systems

Hospice

Home Health

Skilled Nursing Facilities and Nursing Homes

Pharmaceutical and Medical Device

Pharmacy Services

Managed Care

Laboratory, Pathology, Radiology and Diagnostics

Specialty Care and Other Provider Entities

Individual Providers

Miscellaneous/Non-Providers

67.

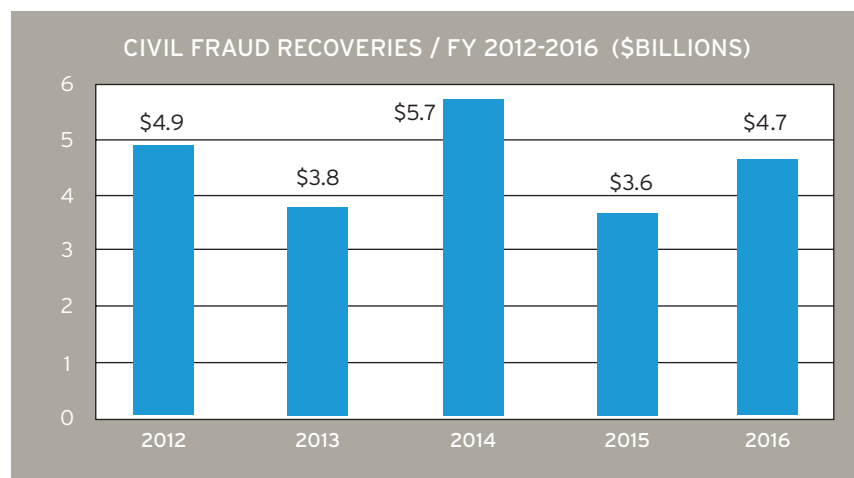
ABOUT BASS, BERRY & SIMS PLC

A LOOK BACK...A LOOK AHEAD

For more than three decades, the government's healthcare fraud enforcement efforts have enjoyed wide bipartisan political support.

Since the amendments to the False Claims Act (FCA) in 1986, results in civil matters involving allegations of healthcare fraud and abuse have amounted to more than \$50 billion in recoveries and have grabbed consistent headlines in the process. And, with the creation of federal and state task forces designed to prosecute misconduct that implicates healthcare fraud statutes, the government has piled up equally impressive criminal enforcement results.

After a slight dip in 2015, civil fraud recoveries by the U.S. Department of Justice (DOJ) rebounded to \$4.7 billion in the fiscal year ending September 30, 2016 (FY 2016). This brought the total of such recoveries to more than \$22.5 billion during the previous five fiscal years. Not surprisingly, the majority of DOJ's civil enforcement recoveries stemmed from matters involving false claims against federal healthcare programs in violation of the FCA.¹



Whistleblowers filed 702 new *qui tam* lawsuits under the FCA in FY 2016, which was a nearly 10% increase compared to the previous year.² Since 2008, relators have filed more than 5,400 *qui tam* lawsuits. For their efforts, whistleblowers recovered \$520 million as their share of proceeds in *qui tam* judgments and settlements in FY 2016, bringing their total recoveries during the past five years to more than \$2.8 billion.³

In FY 2016, the United States recovered \$4.7 billion in fraud-related civil settlements and judgments. During the previous five years, DOJ has recovered more than \$22 billion.

- DOJ Civil Fraud Statistics FY 2016

In addition to civil fraud recoveries, the Medicare Fraud Strike Force announced a number of high-profile criminal enforcement actions and results. In June 2016, the Strike Force announced its largest healthcare fraud takedown in its history, which involved charges against 301 individuals for approximately \$900 million in false billings. The takedown was part of a coordinated nationwide operation across 36 federal districts and involved charges against 60 licensed healthcare professionals, including 30 doctors.⁴ In significant part, the schemes involved alleged fraudulent billings to the federal healthcare programs for services or supplies that were medically unnecessary or not provided, including home health services, durable medical equipment and pharmacy fraud. Since 2011, national healthcare fraud takedowns by the Strike Force have resulted in charges against more than 1,200 individuals involving more than \$3.5 billion in allegedly false or fraudulent billings.

1. <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016>.
2. <https://www.justice.gov/opa/press-release/file/918361/download>.
3. *Id.*
4. <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-301-individuals-approximately-900>.

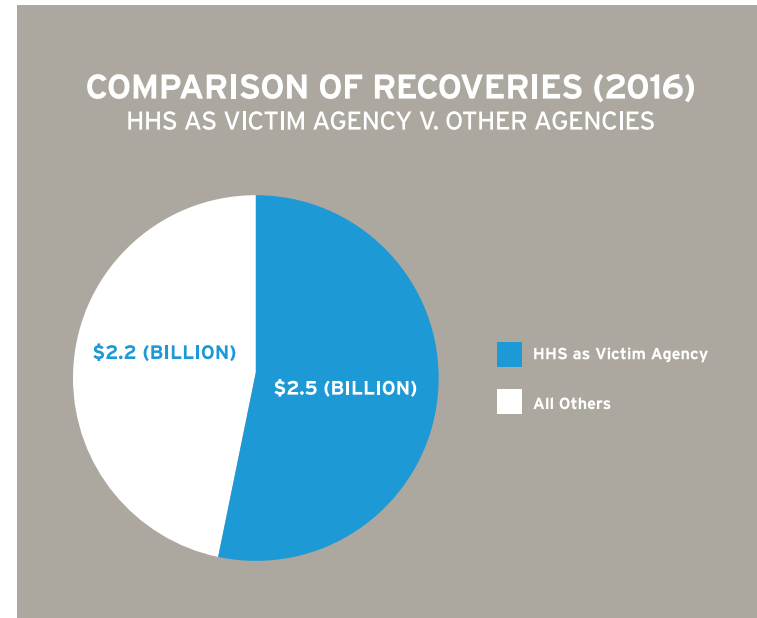
The Strike Force also racked up a number of convictions of healthcare providers, including physicians,⁵ home health,⁶ durable medical equipment suppliers⁷ and ancillary service providers.⁸ The U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) attributed the successful prosecution of healthcare providers, in significant part, to data analytics in identifying outliers and potential bad actors throughout the country.⁹

HHS-OIG reported expected recoveries of more than \$5.66 billion, consisting of nearly \$1.2 billion in audit receivables and approximately \$4.46 billion in investigative receivables.¹⁰ HHS-OIG reported 844 criminal actions against individuals or entities that had engaged in crimes against federal healthcare programs and 708 civil actions, including lawsuits alleging false claims and unjust enrichment and administrative recoveries related to provider self-disclosures.

Relators have filed nearly 3,500 *qui tam* lawsuits during the previous 5 years, including 702 new filings last year.

-DOJ Civil Fraud Statistics FY 2016

HHS-OIG also excluded more than 3,600 individuals and entities from participation in federal healthcare programs. Overall, HHS-OIG reported \$22.1 billion in estimated savings resulting from legislative, regulatory and administrative actions.



5. See, e.g., <https://www.justice.gov/opa/pr/houston-psychiatrist-sentenced-144-months-prison-role-158-million-medicare-fraud-scheme> (hospital psychiatrist sentenced to 144 months as a result of conviction involving \$158 million in false and fraudulent billings to Medicare for partial hospitalization program services); https://www.justice.gov/usao-wdmi/pr/2016_0112_KGandy (physician assistant sentenced to 14 months in prison stemming from scheme to accept kickbacks for patient referrals to medical clinics, physical therapy clinics and a home healthcare agency); <https://www.justice.gov/usao-ndil/pr/oak-brook-doctor-sentenced-two-years-prison-connection-kickback-scheme-sacred-heart> (physician sentenced to 24 months for receiving bribes and kickbacks in exchange for referrals for services billed to federal healthcare programs); <https://www.justice.gov/usao-edmi/pr/detroit-area-neurosurgeon-sentenced-235-months-prison-role-28-million-health-care-fraud> (neurologist sentenced to 235 months in prison stemming from neurologic procedures that were not performed or medically unnecessary services).
6. See, e.g., <https://www.justice.gov/usao-ndil/pr/west-suburban-doctor-sentenced-two-years-federal-prison-falsely-approving-unnecessary> (physician sentenced to 24 months for fraudulently certifying patients as home bound); <https://www.justice.gov/opa/pr/owner-and-manager-three-miami-area-home-health-agencies-convicted-57-million-health-care> (home health agency owner convicted for his role in a fraud scheme involving medically unnecessary home health services and kickbacks to physicians and patient recruiters); <https://www.justice.gov/opa/pr/owner-detroit-home-health-care-agency-sentenced-57-months-prison-his-role-34-million-health> (home health agency owner sentenced to 57 months in prison as a result of scheme to pay physicians kickbacks to refer patients for medically unnecessary home health services); <https://www.justice.gov/usao-ndil/pr/head-schaumburg-home-health-company-sentenced-six-years-scheming-fraudulently-bill> (home health agency head sentenced to 60 months in prison for directing employees to provide medically unnecessary home health services); <https://www.justice.gov/opa/pr/former-owner-and-manager-miami-area-home-health-agencies-sentenced-20-years-prison-role-57> (owners of home health agencies sentenced to 20 years in prison and ordered to pay \$36 million in restitution involving home health services that were unnecessary or not provided); <https://www.justice.gov/opa/pr/detroit-area-home-health-care-agency-owner-sentenced-30-years-prison-33-million-medicare> (home health agency owner sentenced to 30 years in prison for involvement in scheme to pay kickbacks to patient recruiters and provision of medically unnecessary home health services).
7. See, e.g., <https://www.justice.gov/opa/pr/former-owner-and-operator-california-medical-equipment-supply-company-sentenced-their-roles> (DME owner sentenced to 51 months in prison stemming from kickbacks paid to physicians for medically unnecessary power wheelchairs and the resulting false claims); <https://www.justice.gov/opa/pr/owner-los-angeles-medical-supply-company-sentenced-60-months-prison-multimillion-dollar> (owner of medical supply company sentenced to 60 months in prison stemming from billings for unnecessary power wheelchairs, back and knee braces and other medically unnecessary equipment).
8. See, e.g., <https://www.justice.gov/opa/pr/owner-three-los-angeles-clinics-sentenced-78-months-prison-medicare-fraud> (owner of medical clinics sentenced to 78 months in prison for Medicare fraud related to kickbacks paid to patient recruiters and medically unnecessary laboratory tests); <https://www.justice.gov/opa/pr/president-miami-based-transportation-company-convicted-70-million-health-care-fraud-scheme> (transportation company owner convicted in connection with \$70 million fraud scheme to pay kickbacks to patient recruiters); <https://www.justice.gov/opa/pr/former-health-care-clinic-consultant-and-biller-sentenced-135-months-miami-role-63-million> (consultant and biller sentenced to more than 10 years in prison stemming from role in scheme to pay kickbacks and bribes to patient brokers and falsification of medical records to support false and fraudulent claims to Medicare).
9. https://oig.hhs.gov/newsroom/media-materials/2016/2016HealthCareTakedown_FactSheetv2_508.pdf.
10. <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2016/sar-fall-2016-508.pdf>. The investigative receivables more than doubled receivables obtained in FY 2015.

Providers closely watched DOJ pronouncements and enforcement efforts following the September 2015 release of the Yates Memo¹¹ and saw that the policies highlighted by DOJ in the Yates Memo had real teeth. A key component of the Yates Memo was the focus on DOJ's policy of holding individuals accountable in connection with wrongdoing by focusing on such individuals from the inception of civil and criminal corporate investigations. In the year following the release of the Yates Memo, DOJ announced settlements against individuals in a number of high profile cases. For example, in September 2016, the former CEO of Tuomey Healthcare System reached a \$1 million civil settlement stemming from his involvement in Tuomey's illegal billings for services rendered by physicians with whom the hospital had improper financial relationships.¹² The CEO also agreed to a four year exclusion from federal healthcare programs. This settlement followed a \$237.4 million judgment against Tuomey and a resolution of that judgment for payments totaling \$72.4 million and the sale of the hospital.

There were also a number of significant legal developments concerning the FCA. The U.S. Supreme Court tackled one of the most hotly-debated FCA issues regarding the viability of the implied certification theory of liability in **Universal Health Services, Inc. v. U.S. ex rel. Escobar**.¹³ In a unanimous opinion, the Court ruled that the implied certification theory can be a basis for FCA liability and that an express condition of payment in a statutory, regulatory or contractual requirement is relevant—but “not automatically dispositive”—in determining FCA liability. The Court also further clarified how the FCA's materiality requirement should be enforced by lower courts addressing FCA suits premised on an implied false certification theory. How lower federal courts will interpret **Escobar** undoubtedly will be one of the most closely watched issues in the coming year.

We hope our firm's Fifth Annual Healthcare Fraud and Abuse Review will assist healthcare providers in staying abreast of legal developments relevant to their business and will offer insight on what providers might see during the coming year. Whatever uncertainty might ripple through the healthcare industry about what the future may hold, one thing is clear: The government's aggressive healthcare fraud enforcement efforts will continue unabated in the years ahead.

Relator share awards during FY 2016 amounted to nearly \$520 million. Almost 95% of those recoveries were awarded in cases in which the government intervened.

-DOJ Civil Fraud Statistics FY 2016

11. <http://www.justice.gov/dag/file/769036/download>.

12. <https://www.justice.gov/opa/pr/former-chief-executive-south-carolina-hospital-pays-1-million-and-agrees-exclusion-settle>; see also <https://www.justice.gov/opa/pr/north-american-health-care-inc-pay-285-million-settle-claims-medically-unnecessary> (announcing settlement with board chairman (\$1 million) and senior vice president of reimbursement analysis (\$500,000) of North American Health Care following \$28.5 million settlement with the company stemming from scheme to provide medically unnecessary skilled services).

13. https://www.supremecourt.gov/opinions/15pdf/15-7_a074.pdf.

NOTEWORTHY SETTLEMENTS

Resolutions in healthcare fraud cases continued to account for more than half of the FCA recoveries obtained by DOJ in FY 2016.

Of the \$4.7 billion in settlements and judgments—which represents the third highest annual recovery under the FCA—recoveries from the healthcare industry amounted to \$2.5 billion. This is the seventh consecutive year that recoveries in federal civil healthcare fraud matters have exceeded \$2 billion, which does not account for the millions of dollars recovered for state Medicaid programs.¹⁴

While *qui tam* complaints continue to dominate the volume of new fraud matters initiated last year, new non-*qui tam* matters also reflected a remarkable surge in the healthcare context. The healthcare industry experienced a particularly dramatic increase in new non-*qui tam* cases, which jumped to a record-setting 69 new non-*qui tam* cases this year, up from 26 last year. This marked increase in new healthcare fraud matters generated from sources other than *qui tam* complaints indicates healthcare providers remain at the epicenter of the government fraud enforcement efforts.¹⁵

The Appendix to our Healthcare Fraud and Abuse Review contains a detailed breakdown of noteworthy settlements from the past year, many of which are referenced in the following section.

HOSPITALS AND HEALTH SYSTEMS

Last year featured several notable settlements involving hospitals resolving FCA allegations. Most of these settlements related to allegations involving improper physician compensation and billing for medically unreasonable or unnecessary procedures.

Physician Compensation. The 2015 streak of record-breaking FCA settlements related to physician compensation continued this year with a \$513 million blockbuster settlement involving Tenet Healthcare Corporation and two of its Atlanta-based

subsidiaries. The settlement resolved criminal charges and civil claims involving allegations that four of the company's hospitals paid kickbacks to owners and operators of prenatal care clinics in return for referrals of those patients for labor and delivery services in violation of the Anti-Kickback Statute (AKS). As part of the resolution, the company entered a Non-Prosecution Agreement, which carries a three-year term and requires the company to engage a compliance monitor. Among a handful of other resolutions related to physician compensation, a hospital in South Carolina resolved allegations that certain asset purchase agreements or employment agreements violated the Stark Law by agreeing to pay \$17 million and entering in a Corporate Integrity Agreement (CIA).¹⁶ Further detail about these and other settlements is provided in our Stark Law/Anti-Kickback Statute discussion and in the Appendix.

Retention of Overpayments. In a closely watched case involving alleged improperly retained overpayments, Continuum Health Partners and three of its hospitals agreed to pay \$2.95 million to resolve FCA allegations in an intervened *qui tam* action. The government alleged that Continuum improperly retained \$844,000 in overpayments, in violation of the Centers for Medicare & Medicaid Services' (CMS) 60-day overpayment rule. Under the settlement, the defendants admitted that (1) Continuum mistakenly

“Continuum delayed repayment for more than two years and only fully repaid the Medicaid program in 2013. With this settlement, Continuum has made admissions and is paying \$2.95 million for its fraud on Medicaid.”

- DOJ Press Release Announcing FCA Settlement with Continuum Health Partners (Aug. 24, 2016)

14. <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016>.

15. See *id.*

16. <https://www.justice.gov/opa/pr/south-carolina-hospital-pay-17-million-resolve-false-claims-act-and-stark-law-allegations>.

submitted claims to Medicaid for payment due to a software error; (2) Continuum was alerted to the software error by the New York State Comptroller; (3) the whistleblower and other Continuum staff then analyzed billing data to discover possible affected claims; (4) the whistleblower was subsequently terminated; (5) Continuum never brought the whistleblower’s analysis to the attention of the Comptroller; and (6) Continuum did not fully reimburse Medicaid for claims erroneously billed for more than two years.¹⁷

Medical Necessity. Allegations involving medically unnecessary procedures continued to be a persistent theme in enforcement activity against hospitals and healthcare systems. Consistent with prior years, many of these settlements related to medically unnecessary cardiac procedures or studies. Other cases relating to medical necessity covered a range of issues, including length of stay, inpatient status and necessity of particular types of procedures or services.¹⁸ While most of the matters involving medical necessity concerns were settled for relatively lower dollar figures, the high volume of these matters indicate that medical necessity concerns remain a high priority for enforcement authorities.

LONG-TERM CARE PROVIDERS

Long-term care providers, including hospice providers, skilled nursing facilities (SNFs) and home health companies continued to face enforcement scrutiny in the past year. The increase in settlements across these industries demonstrates that DOJ continues to view long-term care providers as high-priority enforcement targets.

Skilled Nursing Facilities. Last year was a record-setting year for DOJ in connection with resolution of FCA allegations against skilled nursing providers, particularly with respect to matters involving medically unnecessary services. These cases involved allegations that providers manipulated patients’ Resource Utilization Group (RUG) levels, such as by providing lower levels of care after the initial assessment reference period, by placing patients in the highest RUG level unless it was shown that patients could not tolerate that amount of therapy, arbitrarily shifting therapy minutes between therapy disciplines to meet RUG targets and recording rounded or estimated minutes instead of the actual amount of therapy provided.¹⁹

COMPARISON OF TOTAL RECOVERIES		
INTERVENED V. DECLINED CASES SETTLEMENTS AND JUDGMENTS (2012-2016)		
YEAR	INTERVENED CASES	DECLINED CASES
2012	\$3.30B	\$ 44.97M
2013	\$2.88B	\$125.82M
2014	\$2.98B	\$80.53M
2015	\$1.76B	\$1.15B
2016	\$491.2M	\$28.4M

Hospice Providers. The government and relators also racked up a number of settlements involving hospice providers. Most of these cases involved allegations that providers had billed Medicare for hospice services for patients who were not eligible for hospice care or had submitted claims for higher levels of care than were appropriate.

For example, Evercare Hospice and Palliative Care agreed to pay \$18 million to resolve FCA allegations in two *qui tam* actions, which were consolidated and litigated after the government’s intervention in 2014. The settlement resolved allegations that Evercare claimed Medicare reimbursement for hospice care for patients who were not eligible for such care because they were not terminally ill and because Evercare’s medical records did not support that they were terminally ill. The government alleged that Evercare’s business practices were designed to maximize the number of patients for whom it could bill Medicare without regard to whether the patients were eligible for and needed hospice.²⁰

17. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-295-million-settlement-hospital-group-improperly>.

18. See, e.g., <https://www.justice.gov/opa/pr/vibra-healthcare-pay-327-million-resolve-claims-medically-unnecessary-services>. (Vibra Healthcare, a national hospital chain, agreed to pay \$32.7 million to resolve FCA allegations it billed Medicare for medically unnecessary services. Specifically, the government alleged that Vibra: (1) admitted patients to five of its long term care hospitals (LTCH) and to one of its inpatient rehabilitation facilities who did not demonstrate signs or symptoms that would qualify them for admission; and (2) extended the stays of its LTCH patients without regard to medical necessity, qualification and/or quality of care—in some instances, allegedly ignoring the recommendations of its own clinicians. As part of the settlement, Vibra entered into a five-year CIA with HHS-OIG).

19. See, e.g., <https://www.justice.gov/opa/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act-allegations> (DOJ announcement that LifeCare Centers of America agreed to pay \$145 million to resolve FCA claims regarding the medical necessity of skilled services); <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-therapy-provider-kindredrehabcare-pay-125-million-resolve-false> (DOJ announcement that Rehab Care and its parent company would pay \$125 million to resolve FCA claims regarding medically unnecessary skilled services).

20. <https://www.justice.gov/opa/pr/minnesota-based-hospice-provider-pay-18-million-alleged-false-claims-medicare-patients-who>.

Home Health Companies. Enforcement activity also remained robust in the home health sector. FCA settlements with home healthcare providers involved a wide range of issues, including billing for medically unnecessary services, AKS violations, failure to comply with requirements such as completing initial certification and “face-to-face” assessments and billing for services provided by an individual excluded from federal and state healthcare programs.

In one of the more noteworthy settlements, the government reached a settlement agreement with the holding company for a regional provider of home-based care (MD2U), its related companies and principal owners (the CEO, CIO and COO), in which the defendants agreed to pay \$3.3 million and a percentage of MD2U's net income over the next five years to resolve FCA allegations that MD2U billed government healthcare programs: (1) for patients who were neither homebound nor home-limited; (2) for medically unnecessary visits; and (3) at the highest payment codes when a lower code would have been more appropriate.²¹ The government also alleged that MD2U cloned medical records through an electronic medical record (EMR) system that allowed for easy cutting, copying and pasting of medical notes from prior visits in order to justify a subsequent patient encounter. Through a stipulation and court order, MD2U and its principal owners admitted to violating the FCA and causing damages of \$21.5 million under the FCA. As part of the settlement, they also entered into a five-year CIA with HHS-OIG.

PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

The pharmaceutical and medical device industry again was responsible for a significant portion of the United States' total healthcare fraud recoveries over the past year. The government resolved cases involving a wide array of misconduct. In previous years, the government settled several cases involving off-label marketing and allegations that manufacturers provided kickbacks to physicians, hospitals or suppliers to induce them to use and/or sell their products. Most notably, Olympus Corporation of the Americas agreed to pay \$623.2 million to resolve criminal charges and civil claims relating to allegations that it provided kickbacks to providers and hospitals in the form of lavish meals, consulting agreements and grants to win new business. To settle the criminal charges, Olympus also agreed to enhance several aspects of its compliance program.²²

This past year, we also witnessed a handful of settlements involving misconduct related to billing and discount practices, including Wyeth and Pfizer which agreed to pay \$784.6 million to resolve allegations that Wyeth failed to notify the government of discounts it provided to hospitals, as required by the Medicaid program.²³ Finally, in the wake of the Yates Memo, DOJ continued to pursue potentially culpable corporate executives, both via criminal charges and civil suits.

21. <https://www.justice.gov/opa/pr/louisville-based-md2u-regional-provider-home-based-care-and-its-principal-owners-admit>.

22. <https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals>.

23. <https://www.justice.gov/opa/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug-rebates>.

ISSUES TO WATCH

Each year, we identify key issues that are likely to drive the government's enforcement efforts in the coming year and that will have a significant impact on how healthcare fraud matters are pursued by relators asserting FCA claims and how they are defended on behalf of healthcare providers.

REPEAL OR MODIFICATIONS TO PPACA

Without question, all healthcare providers will be watching to see whether and to what extent efforts succeed in repealing or modifying all or part of the Patient Protection and Affordable Care Act (PPACA). While keeping tabs on that issue, it is important to remember that PPACA amended the FCA in a number of significant ways, which generally have been considered to be advantageous to the government and relators in pursuing FCA cases, and otherwise included a number of other provisions that will impact fraud and abuse enforcement related to the healthcare industry.

- **Public Disclosure Bar.** PPACA eliminated language in the FCA that provided for a strict, jurisdictional public disclosure bar, and gave the government discretion as to whether the court should dismiss FCA cases on a public disclosure basis. PPACA further limited what would constitute a public disclosure and provided relators with a lower bar to be considered an original source.
- **Overpayments and the 60-day Rule.** Although the FCA already contained a reverse false claims (or retention of overpayments) provision, PPACA amended the FCA to include an explicit obligation that identified overpayments must be returned to the government within 60 days. Failure to do so could lead to liability under the FCA.
- **The Anti-Kickback Statute.** PPACA also amended the AKS to make clear that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." This clarification addressed any lingering uncertainty regarding whether an FCA claim could be based on an underlying AKS violation. PPACA also amended the AKS to provide that in order to establish a violation "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]."

THE YATES MEMO ONE YEAR LATER

Despite the great hullabaloo arising from issuance of the Yates Memo, 2016 did not witness a sudden upsurge in enforcement actions brought against or settlements

with individuals in the healthcare space. The past year did see a handful of significant dollar value settlements with individuals, including George Hepburn (\$10.3 million), the founder and president of Dynasplint Systems Inc.; Dr. Jonathan Oppenheimer (\$9.35 million), former owner and chief executive officer of a drug testing laboratory; and Gottfried and Mieke Kellerman (\$8.5 million), founders of Pharmasan Labs Inc., and NeuroScience Inc. However, it should be noted that the largest healthcare fraud corporate settlements of 2016 (for example, with **Wyeth, Pfizer, Novartis, Millenium Health, and Tenet**) have not included – at least not to date – concomitant settlements with individuals at any of those companies.

Although not the largest amount paid by an individual in 2016, the settlement that received the most attention was that of Ralph J. Cox, the former CEO of Tuomey Healthcare System. In 2015, the Fourth Circuit upheld a jury verdict against Tuomey of \$237.4 million relating to findings that the hospital entered into employment agreements that violated the Stark Law. Tuomey ultimately settled with DOJ for \$72.4 million but Cox did not receive a release in that settlement. In September 2016, Cox settled with DOJ for \$1 million and agreed to be excluded from federal healthcare programs for four years.

That is not to say that the Yates Memo is having no impact in how cases are investigated or resolved. On a practical level, there is no longer any expectation that an FCA settlement with a corporate defendant will include releases for any individuals associated with the company. Additionally, DOJ does appear to be putting a greater focus on obtaining information relating to individuals at earlier stages in cases, including (in our experience) an increase in the number of CIDs being issued to individual executives of companies in connection with investigation of the companies. Also, the requirement that DOJ attorneys put in writing their recommendations for any individual against whom DOJ decides not to pursue recovery has had the general effect of delaying the settlement process.

The Yates Memo has continued to be a very hot topic on the speaking circuit. Of particular note from 2016 are four key points from remarks made by Acting

Associate Attorney General (AAG) Bill Baer in June 2016. First, companies that want DOJ to “credit cooperation” must “disclose all facts relating to the individuals involved in the wrongdoing, no matter where those individuals fall in the corporate hierarchy.” Second, providing this information may entail providing information even beyond what has been “requested by the government.” Third, DOJ does not expect companies to assess culpability of individuals, which DOJ says is its job, but to provide “all facts” so that DOJ can “understand the conduct that occurred and who was involved or sanctioned it.” Fourth, nothing in DOJ’s policies regarding credit cooperation requires the waiver of the attorney-client privilege. Despite these comments from Acting AAG, one that remains unclear is what cooperation credit actually consists of or amounts to.

Although it is too early to draw conclusions, the activity on individual liability in 2016 (or the lack thereof) lends credence to the view that the Yates Memo was not a sea change in DOJ policy as much as a loudly-broadcast reminder for prosecutors to consider not just corporate liability, but individual liability as well. It also remains to be seen whether new leadership at DOJ will alter or seek to supersede any of the directives in the Yates Memo. Early indications are that increased efforts to hold individuals accountable will continue.

SHIFT TO VALUE-BASED PAYMENT METHODOLOGIES²⁴

Healthcare providers also are facing rapid changes to healthcare payment and delivery models as CMS shifts from fee-for-service to value-based payment methodologies. This shift also will result in new fraud and abuse risks as providers navigate these changes.

CMS intends to move 50% of traditional fee-for-service Medicare payments to value-based alternative payment methodologies by the end of 2018. At the end of 2016, CMS met its interim goal, tying 30% of Medicare payments to alternative payment models. Value-based payment models aim to reward healthcare providers for the quality of care and efficiency of services provided, or achievement of cost reductions, rather than the volume of services. CMS anticipates that this move will encourage coordination of care and a more seamless approach to patient treatment across providers.

Historically, the federal fraud and abuse laws, such as the federal physician self-referral law, or Stark Law,²⁵ AKS²⁶ and Civil Monetary Penalty (CMP) laws prohibiting beneficiary inducements²⁷ (collectively, Fraud and Abuse Laws), led to increased scrutiny when healthcare providers work together or offer incentives to patients related to their care. In the traditional fee-for-service payment model, a collaborative arrangement could pose risks of overutilization or improper cross-referrals. Thus, providers who partnered together did so at their own risk if the collaboration was later judged by a regulator or whistleblower to be an improper referral arrangement. The new value-based methodologies, however, can only achieve the desired quality and cost savings with coordination of care among providers.

To address the inconsistency between the Fraud and Abuse Laws and the move to value-based payments, and as required by PPACA to allow the arrangements envisioned by the Medicare Shared Savings Programs (MSSP), CMS and HHS-OIG established a number of waivers to structure an arrangement envisioned by the MSSP. The waivers generally function like AKS safe harbors in that the arrangement is protected if all of the conditions of the waiver are satisfied.

While the waivers provide flexibility to achieve compliance under the new payment methodologies, they also add new requirements that must be met to ensure ongoing compliance and require detailed tracking of the activities among providers. Additionally, the waivers do not obviate the need to comply with basic requirements, such as ensuring arrangements are at fair market value and commercially reasonable, under the Fraud and Abuse Laws. Failure to comply with these laws could lead to massive damages and penalties, particularly under the FCA.

As new payment models are increasingly employed, FCA theories of liability will adapt to these models. For example, if a provider certifies that it has achieved certain quality metrics in order to obtain incentive payments, but that certification is found to be knowingly false, a relator or the government could seek to hold the provider liable under the FCA.²⁸ The greater the proliferation of attestations that becomes necessary to make in connection with submission of quality data, the more likely plaintiffs can find ways to challenge the correctness of those attestations. Even if the total incentive payments received are not significant, providers still could be subject to substantial

24. Anna Grizzle, Adrienne Kepner Laraby, Amy Morgan & Brian Roark, *New in Old Wineskins: Mitigating Fraud and Abuse Risks in Value-Based Reimbursement*, AHLA Connections, February 2017. This section is an excerpt from the noted article and was reprinted with permission from the February 2017 edition of AHLA Connections. © 2017 American Health Lawyers Association. American Health Lawyers is the publisher and editor of this work and holds the exclusive license. Further reproduction requires the advance written permission of American Health Lawyers Association.

25. 42 U.S.C. 1395nn.

26. 42 U.S.C. §1320a-7b.

27. 42 U.S.C. §1320a-7a(a)(5).

28. See *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016) (discussing FCA false certification liability).

penalties if a plaintiff could show that providers were seeking the payments on a per-claim basis.

Plaintiffs could seek to use quality measures to bolster so-called “quality of care” cases brought pursuant to the FCA that seek to hold providers liable for sub-standard care. Most courts have held that the FCA cannot be used to pursue low quality of care unless the care was of such poor quality to amount to worthless or no services at all.²⁹ However, to the extent that quality measures come to be identified with federally-defined standards of care for practice, a relator or the government could seek to hold providers liable for submission of false claims for knowing failure to meet those standards of care.³⁰ The impact of these changes to payment methodologies will continue to be an area to watch in the coming years.

29. See, e.g., *U.S. ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699 (7th Cir. 2014).

30. See *U.S. v. Villaspring Health Care Center, Inc.*, 2011 WL 6337455, *5 (E.D. Ky. Dec. 19, 2011) (when alleging claims for worthless services, “[i]t is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that ‘patients were not provided the quality of care’ which meets the statutory standard”).

FALSE CLAIMS ACT UPDATE

The FCA is the federal government's primary civil enforcement tool for investigating allegations that healthcare providers defrauded the federal healthcare programs.

As in previous years, there continue to be a number of legal developments involving the FCA that will greatly impact the government's enforcement efforts.

ESCOBAR AND ITS AFTERMATH

Perhaps the most significant FCA development last year was the U.S. Supreme Court's decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*.³¹ In *Escobar*, the Supreme Court addressed the viability of the implied certification theory of liability, whether an express condition of payment is required for FCA liability and the applicable standard and contours of the FCA's materiality requirement. In the latter half of this year, lower courts began wrestling with how to apply the Court's seminal decision.

The U.S. Supreme Court's *Escobar* Decision

In *Escobar*, the relators alleged that Universal Health Services (UHS) violated the FCA by submitting claims for services provided at a mental health clinic that failed to comply with Medicaid regulations related to staff licensure and supervision. The relators alleged UHS impliedly certified compliance with these regulations and by failing to disclose the purported noncompliance, the claims were rendered false under the FCA. In 2014, the district court granted UHS's motion to dismiss, concluding the regulations at issue were conditions of participation in the Massachusetts Medicaid program, not conditions of payment, and therefore, could not form the basis of an implied false certification claim. The First Circuit reversed, holding that a condition of payment need not be expressly designated and that whether a regulatory requirement is a condition of payment is a fact-intensive and context-specific inquiry.

The Supreme Court granted certiorari to address two questions: (1) is the implied certification theory under the FCA viable?³² and (2) if so, does liability under the theory require that the underlying statute, regulation or contractual

provision expressly state that it is a condition of payment?³³

Viability of Implied Certification Theory. The Supreme Court first held that the "implied false certification theory can, at least in some circumstances, provide a basis for liability." One such circumstance is when: (1) the defendant submits a claim that "does not merely request payment, but also makes specific representations about the goods or services provided," and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations half-truths." In other words, when "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided."

The Supreme Court found that the relators pleaded actionable misrepresentations because the claims for payment "us[ed] payment codes that corresponded to specific counseling services" and "National Provider Identification numbers corresponding to specific job titles." These representations, the Court explained, conveyed to the reader that the mental health clinic's personnel had certain training, experience and qualifications required by Medicaid regulations—which, according to the relators' allegations, was not the case.

"What matters is not the label the government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision."

- *Universal Health Services, Inc. v. U.S. ex rel. Escobar*

31. 136 S. Ct. 1989 (2016).

32. Compare *Mikes v. Straus*, 274 F.3d 687 (2d. Cir. 2001) (accepting implied certification theory), with *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015) (generally rejecting implied certification theory).

33. Compare *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011) (express condition of payment not required), with *U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 715 (6th Cir. 2013) (no condition of payment where one must "weav[e] together isolated phrases from several sections in the complex scheme of Medicare regulations").

Conditions of Payment and the “Demanding” Materiality Requirement. The Supreme Court also held that the FCA does not restrict liability to noncompliance with express conditions of payment, stating that “[w]hether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.” The Supreme Court explained that any concerns about fair notice or open-ended liability without such a restriction on liability can be addressed through “strict enforcement” of the FCA’s “demanding” and “rigorous” materiality requirement, as well as the FCA’s scienter requirement.

Significantly, the Supreme Court rejected the government’s and First Circuit’s “extraordinarily expansive view” of materiality—that any statutory, regulatory or contractual violation is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation. Instead, the Supreme Court explained that the materiality requirement focuses on whether knowledge of noncompliance would affect “the *likely or actual* behavior of the recipient of the alleged misrepresentation,” not simply on whether the recipient’s behavior *could* have been affected.

The Supreme Court noted that the FCA’s materiality requirement safeguards defendants from FCA liability for “garden-variety breaches of contract or regulatory violations” and is not satisfied “where noncompliance is minor or insubstantial.” To further delineate when the nondisclosure of a legal violation is material, it offered the following evidentiary guideposts:

- It is not sufficient for a finding of materiality that the government “would have had the option to decline to pay if it knew of the defendant’s noncompliance.”
- The government’s decision to “expressly identify a provision as a condition of payment is relevant, but not automatically dispositive” of the materiality inquiry.
- It is evidence of materiality “that the defendant knows that the government consistently refuses to pay claims in the mine run of cases based on noncompliance” with a requirement.
- It is “[v]ery strong evidence” of immateriality “if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated.”
- It is “[s]trong evidence” of immateriality “if the government regularly pays a

particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position.”

Addressing UHS’s concern that materiality is “too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss or at summary judgment,” the Supreme Court indicated that lack of materiality remains a basis for dismissal, noting that relators and the government still must plead their claims with plausibility and particularly under Federal Rules of Civil Procedure 8 and 9(b), “by, for instance, pleading facts to support allegations of materiality.”³⁴

FCA CASES FOLLOWING ESCOBAR

The Supreme Court’s **Escobar** opinion left many unanswered questions as to the scope of the implied certification theory and the application of the “demanding” materiality requirement, and not surprisingly, lower courts have varied significantly in how they have applied the Court’s decision.

Implied Certification. Lower courts have disagreed as to whether the two conditions set forth by **Escobar** for stating an implied certification claim—(1) that a claim makes representations about the services provided and (2) that defendant’s failure to disclose noncompliance makes the representations misleading half-truths—represent the only viable path or just one possible option. In **U.S. ex rel. Doe v. Health First, Inc.**, the district court took the former view, stating that under **Escobar** the “two conditions must exist” for implied certification liability.³⁵ In **U.S. v. Sanford-Brown, Ltd.**, the Seventh Circuit found that the two conditions had not been met, yet did not consider whether the implied certification theory might be tenable in other circumstances.³⁶

However, noting that **Escobar** held implied certification could be a viable theory “at least” where the two conditions were met, other courts have concluded that **Escobar** does not present the only way to state an implied certification claim. For example, in **Rose v. Stephens Institute**, the district court explained that **Escobar** did “not purport to set out, as an absolute requirement, that implied false certification liability can attach *only* when these two conditions are met.”³⁷ It remains to be seen whether and how other courts will flesh out the contours

34. On remand, the First Circuit found that the alleged violations were material. First, the court noted that relators alleged “regulatory compliance was a condition of payment.” Second, the court believed the centrality of the licensing and supervision requirements in the MassHealth regulatory program went to the “very essence of the bargain.” And, third, the court found no evidence in the record that MassHealth paid claims despite knowing of the violations. *U.S. ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110-11 (1st Cir. 2016).

35. 2016 WL 3959343 (M.D. Fla. July 22, 2016).

36. 840 F.3d 445 (7th Cir. 2016).

37. 2016 WL 5076214 (N.D. Cal Sept. 20, 2016) (appeal pending); see also *U.S. ex rel. Panarello v. Kaplan Early Learning Co.*, No. 11-cv-00353, Dkt. No. 96 (W.D.N.Y. Nov. 14, 2016) (report and recommendation) (appeal to district court pending).

of potential implied certification theories that differ from that espoused in **Escobar**.

Regardless, the “specific representation” requirement may often be met in the healthcare context, where claims typically specify the services provided. For instance, in **U.S. v. Crumb**, the district court explained, “[a]s to [**Escobar**’s] first requirement, the Amended Complaint clearly alleges that the Form CMS-1500 claims ... were much more than bare requests for payment, but also made specific representations about the services provided and the reasons for those services (i.e., diagnoses).”³⁸

“The materiality standard is demanding.... A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.”

-*Universal Health Services, Inc. v. U.S. ex rel. Escobar*

Application of Escobar’s Materiality Standard. Two of the most significant takeaways from **Escobar** are that statutory, regulatory and contractual violations by themselves may not be material, even if the provisions are expressly labeled as conditions of payment, and that the government’s decision to pay claims despite actual knowledge of violations is particularly good evidence of immateriality. Since **Escobar**, courts have varied in how they have applied these two aspects of the materiality analysis.

Several courts dismissed complaints that alleged only that the defendant violated

a condition of payment or simply that the government would have denied payment if it had known of the noncompliance. In **U.S. ex rel. Lee v. Northern Adult Daily Health Care Center**, the relators alleged that the defendant violated statutes and regulations that were conditions of payment. The district court recognized that, while this allegation might have sufficed before **Escobar**, it could not meet the Supreme Court’s new standard.³⁹

In **U.S. ex rel. Dresser v. Qualium Corp.**, the district court dismissed the government’s implied certification claims where the complaint asserted that the government would not have paid the defendants’ claims if it had known of their alleged noncompliance with Medicare regulations, “but [did] not explain why” that was the case.⁴⁰ A similar conclusion was reached in **U.S. ex rel. Southeastern Carpenters Regional Council v. Fulton County, Georgia**, where the district court held that the defendant’s alleged statutory violations were not material even where the defendant’s contract required it to comply with the statute and made that compliance a condition of payment.⁴¹ According to the district court, these allegations were insufficient under **Escobar** to show that the statutory violations were “so central” that the government would have refused payment if it had known of the violations.

Other courts held that statutory, regulatory and contractual violations were material under **Escobar**. In **U.S. ex rel. Fisher v. IASIS Healthcare, LLC**, the relators accused the defendant of violating regulatory and contractual provisions that required the defendant to provide truthful encounter data and medically necessary care.⁴² The district court acknowledged that “[a] legal or contractual violation alone is not enough,” but found that the alleged violations were material because the government’s “payments were contingent on compliance with the terms and conditions of that contract.”

Similar reasoning was employed by the district court in **Johnson v. District of Columbia**, where the district court applied **Escobar** to the District of Columbia’s FCA Statute and found materiality satisfied where the defendant submitted false information to hide its failure to meet certain performance benchmarks.⁴³ The district court found the false statements were “undoubtedly” material because the defendant’s contract permitted the government to terminate the agreement or reduce payment for failure to meet those benchmarks or to comply with reporting requirements.

38. 2016 WL 4480690 (S.D. Ala. Aug. 24, 2016).

39. 2016 WL 4703653 (E.D.N.Y. 2016).

40. 2016 WL 3880763 (N.D. Cal. July 18, 2016).

41. 2016 WL 4158392 (N.D. Ga. Aug. 5, 2016).

42. 2016 WL 6610675 (D. Ariz. Nov. 9, 2016).

43. 144 A.3d 1120 (D.C. 2016).

Likewise, in **U.S. v. Crumb**, where the defendants allegedly falsified diagnoses on billed claims, the district court found the defendant's failure to adhere to diagnostic requirements was material because the "services would not have been reimbursable unless they were provided for a covered diagnosis."⁴⁴

The tension between these two lines of post-**Escobar** cases suggests that while some courts will hold that statutory, regulatory and contractual violations are not enough to satisfy the materiality requirement, even if they would entitle the government to deny payment, other courts will look closely at the specific provisions at issue to determine whether the alleged violations are material. In a pre-**Escobar** case from last year, **U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.**, the Tenth Circuit held that, in addressing materiality, it would "consider the purposes of the underlying contract and the significance of the relevant violation to that purpose in assessing whether the alleged violation may have affected the government's payment decisions."⁴⁵ This accurately describes the analysis the latter courts have applied.

Some courts have used government knowledge as a basis for dismissing FCA claims. In **Sanford-Brown**, the Seventh Circuit held that the relator failed to show materiality where government agencies, including the agency that paid the defendant's claims, had "already examined [the defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted."⁴⁶ A similar result was reached in **City of Chicago v. Purdue Pharma L.P.**, where the district court held that the alleged violations were not material because the city continued to pay the defendant's allegedly false claims after filing the lawsuit.⁴⁷ The district court rejected the city's argument that it lacked actual knowledge that the claims were false, reasoning that the city could not disclaim actual knowledge of falsity after suing for a violation of the FCA.

In addition, several courts have dismissed complaints that did not allege government nonpayment. In **Scharff v. Camelot Counseling**, the district

court dismissed the relator's complaint where it did not "allege whether the government has refused to reimburse clinics that have engaged in conduct similar to [the defendant's]."⁴⁸ And, in **U.S. ex rel. Williams v. City of Brockton**, the district court held that the alleged statutory violations were not material because the government would pursue administrative remedies before denying payment.⁴⁹

Still, other courts have rejected defendants' arguments regarding government knowledge. On remand from the Supreme Court in **Escobar**, UHS argued that its alleged violations could not be material because the government paid its claims after learning of the alleged noncompliance.⁵⁰ The First Circuit disagreed, reasoning that the government's "mere awareness of allegations concerning noncompliance" did not constitute "actual knowledge," and that even if it did, there was no evidence that the government entity that actually paid the claims had actual knowledge. In other words, actual knowledge possessed by separate, non-paying government regulators would be irrelevant to materiality.

Likewise, in **Rose v. Stephens Institute**, the district court found that the government's decision not to take action against the defendant despite its awareness of the relator's allegations was "not terribly relevant to materiality."⁵¹ Because the government "did not cite any reason for this decision," the district court could not conclude that the government had actual knowledge of the violations or that it declined to act because it considered the violations immaterial. The district court further found that the government's decision to issue fines and enter monetary settlements for similar violations committed by other entities was evidence of materiality, even though the government had never terminated those entities' participation in the program.⁵²

Finally, it is worth noting that the government-knowledge factor pre-dates **Escobar**, and several federal circuits have well-developed case law applying this factor.⁵³ Courts likely will rely on this precedent as they continue to grapple with **Escobar**'s materiality standard.

44. 2016 WL 4480690 (S.D. Ala. Aug. 24, 2016).

45. 820 F.3d 1162, 1174 (10th Cir. 2016).

46. 840 F.3d 445 (7th Cir. 2016).

47. 2016 WL 5477522 (N.D. Ill. Sept. 29, 2016).

48. 2016 WL 5416494 (S.D.N.Y. Sept. 28, 2016); see also *Knudsen v. Sprint Commc'ns. Co.*, 2016 WL 4548924 (N.D. Cal. Sept. 1, 2016) ("Knudsen's single, conclusory paragraph alleging materiality is insufficient on this ground as well because it did not further allege that the government was unaware of the alleged PRC violations."); *U.S. ex rel. Ferris v. Afognak Native Corp.*, No. 3:15-cv-0150 (D. Alaska Sept. 28, 2016) ("The relator must allege some facts that show that the government actually does not pay claims if they involve the statutory violations in question.").

49. 2016 WL 4179863 (D. Mass. Aug. 5, 2016).

50. 842 F.3d 103 (1st Cir. 2016).

51. 2016 WL 5076214 (N.D. Cal. Sept. 20, 2016).

52. In *United States v. Family Med. Ctrs. of South Carolina, LLC*, 2016 WL 6601017 (D.S.C. Nov. 8, 2016), the district court held that because materiality focuses on whether the false statement is capable of influencing the government at the time of presentment, the government's decision to continue paying the defendants' claims even after filing the lawsuit was not evidence of a lack of materiality. It is difficult to square this reasoning with *Escobar*'s declaration that if the government pays the claims at issue despite actual knowledge of their falsity, this is "very strong" evidence that of immateriality.

53. See *U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1174 (10th Cir. 2016); *U.S. ex rel. Am. Sys. Consulting, Inc. v. ManTech Advanced Sys. Int'l*, 600 F. App'x 969, 977 (6th Cir. 2015); *Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 828, 831 (7th Cir. 2011); *U.S. ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 729 (4th Cir. 2010).

DEVELOPMENTS IN FCA PLEADING STANDARDS

Pleading with Particularity under Rule 9(b)

Federal courts continued to examine the particularity of the pleading required by Rule 9(b) in the context of FCA claims. Although courts generally agree that a relator must plead the “who, what, when, where, and how” of the alleged fraud, the manner in which courts applied this standard and the types of allegations considered sufficient to satisfy Rule 9(b) continues to vary significantly.

Pleading Actual Claims

A number of courts continued to impose a strict requirement that relators identify and plead the specific details of a false claim, though many courts have identified limited circumstances in which application of a more flexible pleading standard may be appropriate. For example, this year, courts in the Sixth Circuit repeatedly dismissed complaints for failure to plead actual false claims; the Sixth Circuit, however, for the first time relaxed the pleading standard when a relator alleged personal knowledge of billing practices without pleading a particular false claim. The First Circuit continued to apply a more flexible standard when a complaint alleges the defendant *caused* the submission of false claims. Though these cases indicate that some courts recognize a more permissive standard for satisfying Rule 9(b) in certain circumstances, they also demonstrate that even these relaxed standards can be quite demanding.

Cases Requiring the Pleading of Actual False Claims. A number of courts continued to dismiss complaints based on relators’ failure to identify an actual false claim, while leaving open the possibility that certain circumstances may warrant application of a more permissive approach. For example, in *U.S. ex rel. Eberhard v. Physicians Choice Laboratory Services, LLC.*, the Sixth Circuit applied the Circuit’s “strict” standard to dismiss the complaint when the relator failed to identify the “time, place, and content of [the defendant’s] alleged misrepresentation.” Consistent with prior decisions, the Sixth Circuit left open the possibility that certain circumstances may warrant the application of a more flexible standard, though declined to do so in this case.⁵⁴

Similarly, in *U.S. ex rel. Chase v. LifePath Hospice, Inc.*, the U.S. District Court for

the Middle District of Florida dismissed a complaint because the relator did “not identify a single claim submitted to the government, let alone a false one.” Citing an unpublished decision from the Eleventh Circuit, the district court acknowledged that a complaint alleging “strong indicia of reliability *vis-à-vis* the fraudulent claim” could permit a complaint to survive Rule 9(b)’s particularity requirement. The district court concluded, however, that the complaint did not include such indicia because it lacked allegations that the relator had “first-hand knowledge of billing practices.”⁵⁵

At least one case this year provided a helpful illustration of the granular detail necessary to survive the stringent requirement that actual claims be pleaded with particularity. In *U.S. ex rel. Lee v. Northern Adult Daily Health Care Center*, the district court partially denied a motion to dismiss when the relator pleaded actual false claims by providing an annex with billing details for 16 claims. The district court held the relator pleaded actual claims with sufficient particularity by providing details such as the relevant “dates of attendance, Defendants’ misconduct, and the facts that render Defendants’ claims false.”⁵⁶

Circumstances Permitting Application of a More Permissive Standard. When courts applied a more permissive pleading standard last year, they did so in two limited circumstances. Some courts relaxed the Rule 9(b) standard when a complaint pleaded facts that support a “strong inference” that claims were actually submitted, such as the relator’s personal knowledge of the submission of claims or regarding the relevant billing practices. The First Circuit also applied a more flexible standard in cases involving allegations that the defendant caused a third party to submit false claims.

As noted above, courts in the Sixth Circuit have dismissed numerous cases for failure to plead an actual claim, while leaving open the possibility that a relaxed standard may be appropriate under certain circumstances. This year, the Sixth Circuit applied a relaxed standard for the first time. In *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, the relator alleged in relevant part that she was hired to work through a back log of final Medicare claims, that she had been responsible for “reviewing the documentation for those Medicare claims, *in anticipation of them being submitted to Medicare*[,]” and that she “received confirmation that the final claims that she reviewed were submitted for payment.”⁵⁷ Because these allegations, which were “based on her personal billing-related knowledge,” supported a “strong

54. 642 Fed. Appx. 547, 550-51, 553 (6th Cir. 2016) (citing *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493 (6th Cir. 2007) and *Chesborough v. VPA, P.C.*, 655 F.3d 461 (6th Cir. 2011)); see also *U.S. ex rel. Crockett v. Complete Fitness Rehab., Inc.*, 2016 WL 5476277, at *9 (E.D. Mich. Sept. 29, 2016) (failure “to identify a fraudulent claim” was “fatal to [the] complaint”); *U.S. ex rel. Armes v. Garman*, 2016 WL 3562062, at *9 (E.D. Tenn. June 24, 2016) (dismissing complaint because relator failed to allege false claims and did not allege any “personal

knowledge of any claims or billing information” to justify the application of a relaxed standard).

55. 2016 WL 5239863, at *8 (M.D. Fla. Sept. 22, 2016) (citing *U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 Fed. Appx. 693 (11th Cir. 2014)).

56. 2016 WL 4703653, at *7 (E.D.N.Y. Sept. 7, 2016).

57. 838 F.3d 750, 770 (6th Cir. 2016).

inference that specific false claims were submitted for payment,” the Sixth Circuit determined that it was appropriate to relax the requirement that a relator identify an actual false claim and held the relator had satisfied Rule 9(b).⁵⁸

A series of First Circuit cases continued to apply a “more flexible” Rule 9(b) standard in circumstances involving allegations that the defendant *caused* third parties to submit false claims. Under these circumstances, the First Circuit allows a relator to overcome a Rule 9(b) challenge by providing “factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim.”⁵⁹ To satisfy this standard, a relator must provide details such as the providers involved in submitting the allegedly false claims, the “rough time periods, locations, and amounts of the specific false claims,” and the government programs to which claims were submitted.⁶⁰ Despite applying this lower threshold, the First Circuit held the relators failed to satisfy Rule 9(b) in all four cases it considered this year.⁶¹ Thus, while the First Circuit applies a “more flexible” standard to complaints alleging that a defendant caused another party to submit false claims, even under these circumstances, the particularity requirements remain fairly rigid.

Pleading the Circumstances of Fraud

Courts continued to scrutinize FCA complaints to determine whether they sufficiently pleaded the circumstances of a fraudulent scheme – the “who, what, when, where, and how” of the alleged fraud. While courts consistently dismissed allegations that failed to specify “how” conduct was fraudulent, they varied in their analysis of whether the “who” was pleaded sufficiently. In addition, one court addressed the circumstances in which allegations of a nationwide scheme could be sufficient to support claims based on conduct in multiple states.

Courts consistently dismissed complaints in which the relator did not specify “how”

the alleged misconduct amounted to fraud. For example, in ***U.S. ex rel. Scharff v. Camelot Counseling***, the district court held that allegations regarding deficient documentation and signatures failed to satisfy Rule 9(b) because the relator did not allege “the level of detail required of patient notes” and “fail[ed] to allege with particularity why these practices were fraudulent, as opposed to sloppy.”⁶² Similarly, in ***U.S. ex rel. Kalec v. Nuwave Monitoring, LLC***, another district court reasoned that allegations regarding inflated technician time failed to satisfy Rule 9(b) because the relators did not “specifically plead how Medicare requires technician neuro-monitoring services to be billed, thereby failing to adequately allege that Medicare prohibited [the defendant’s] technician billing practices.”⁶³ Finally, another district court noted a relator could not satisfy Rule 9(b) by specifying how particular conduct would be fraudulent “if” that conduct occurred without having alleged the conduct, in fact, did occur.⁶⁴

Several decisions resulted in nuanced distinctions between the ways in which different courts analyzed whether the “who” had been sufficiently pleaded. For example, two district courts appeared to take different approaches with regard to whether a relator must specify the doctors or coders involved in generating allegedly fraudulent documentation.⁶⁵ In the context of FCA allegations based on purported AKS violations, one district court held the relators failed to satisfy Rule 9(b) because the complaints did not identify who at the defendant company “participated in the agreement to violate the AKS” or any involvement by the defendant-owners.⁶⁶

The requisite level of particularity required when alleging different types of nationwide schemes was considered in ***U.S. ex rel. Polansky v. Executive Health Resources, Inc.*** There, the relator alleged Executive Health Resources (EHR), a physician advisory company, caused its hospital clients to falsely bill patient admissions as inpatient when they should have been billed as outpatient. While specific allegations

58. *Id.* at 773; see also *U.S. ex rel. Schramm v. Fox Valley Physical Servs.*, 2016 WL 537951, at *5-6 (complaint satisfied Rule 9(b) because “the defendants are adequately on notice of the false claims and misconduct alleged” by allegations that identified 10 patients who received the allegedly non-compliant services at issue during a four-month timeframe and claimed an employee responsible for billing stated the allegedly fraudulent claims would be submitted).

59. *U.S. ex rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016) (citing *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29-30 (1st Cir. 2009)).

60. *Id.* (quoting *U.S. ex rel. Ge v. Takeda Pharm. Co., Ltd.*, 737 F.3d 116, 121, 124 (1st Cir. 2013)).

61. See *Hagerty ex rel. U.S. v. Cyberonics, Inc.*, 2016 WL 7321224, at *4 (1st Cir. 2016) (complaint did not satisfy Rule 9(b) by failing to specify approximate volume of affected claims, how the claims were false, whether relevant patients were covered by federal healthcare programs, and whether providers submitted claims for these services); *Lawton ex rel. U.S. v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 131 (1st Cir. 2016) (complaint failed to provide the requisite amount of particularity because it failed to specify “who submitted false claims to the government, how many false claims were submitted to the government, or how the Defendants’ actions resulted in the submission of false claims”); *Kelly*, 827 F.3d at 14-15 (allegations that certain doctors who (1) received incentives from the defendants, (2) prescribed the medication at issue, and (3) were enrolled in federal reimbursement programs did not satisfy Rule 9(b) because the relator did not “tie these independently unexceptional allegations together into particularized charges about specific fraudulent claims for payment.”); see also *D’Agostino v. ev3, Inc.*, 2016 WL 7422943, at *8 (1st Cir. Dec. 23, 2016).

62. 2016 WL 5416494, at *4-5 (S.D.N.Y. Sept. 28, 2016).

63. 2016 WL 750155, at *7 (N.D. Ill. Jan. 26, 2016).

64. *U.S. ex rel. Hockenberry v. OhioHealth Corp.*, 2016 WL 4480350, at *6 (S.D. Ohio Aug. 25, 2016).

65. Compare *Hockenberry* 2016 WL 4480350, at *6 (allegations failed to satisfy Rule 9(b) when relator alleged he “observed first hand Defendants’ employees” engaged in upcoding because he failed to identify physicians involved in upcoding or patients affected) with *U.S. ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, 2016 WL 5661644, at *6 (N.D. Tex. Sept. 30, 2016) (complaint was “not fatally deficient . . . [due to the fact] it does not name a physician who made an allegedly false diagnosis or a coder who entered an allegedly false code” when the relator sufficiently pled she “personally observed the conduct” at issue and named an employee who allegedly “acted in furtherance of the scheme”).

66. 2016 WL 750155, at *7 (N.D. Ill. Jan. 26, 2016); see also *U.S. ex rel. Driscoll v. Todd Spencer M.D. Med. Grp.*, 2016 WL 7229135, at *5 (E.D. Cal. Dec. 14, 2016) (relator failed to satisfy Rule 9(b) when alleging FCA liability based on a false certification theory because complaint did not identify who provided certification at issue).

“Because a difference of opinion between physicians and medical experts about which reasonable minds could differ is all the Government has presented to prove falsity of the claims ... at issue, the Government cannot prove the falsity element as a matter of law.”

-*U.S. ex rel. Paradis v. AseraCare, Inc.*

pertained only to conduct in four states, the district court allowed claims to proceed under dozens of state laws based on the alleged nationwide scheme, which centered on the criteria and processes EHR employed for all its case reviews. Analogizing to cases alleging FCA liability based on AKS violations, the district court reasoned the alleged scheme was more like “a uniform nationwide marketing and kickback scheme” than one in which kickbacks “varied by the medical provider” who was “targeted.” The district court concluded that the relator had “alleged the nationwide scope of EHR’s scheme with sufficient particularity.”⁶⁷

Developments Regarding Falsity and Materiality

While *Escobar* and subsequent lower court decisions interpreting *Escobar* have been the most discussed topic this year, courts have addressed other notable issues regarding the FCA’s falsity and materiality requirements, including whether the government and relators can rely on subjective medical opinions (i.e., not objective falsehoods) and statistical sampling in establishing falsity.

Express Certification

While *Escobar* focused on implied certification liability, its guidance as to the FCA’s materiality requirement should apply equally to FCA cases where falsity is premised on an express certification.⁶⁸ In addition, although *Escobar* did not discuss the parameters of the express false certification theory of liability, it did disavow open-ended FCA liability, remarking that “if the Government required contractors to aver

their compliance with the entire U.S. Code and Code of Federal Regulations,” then “failing to mention noncompliance with any of those requirements would always be material,” which is “an extraordinarily expansive view of liability” that the FCA “does not adopt.”

How courts view the scope of the express certification requirement and whether courts apply the materiality requirement as strongly in express certification cases will be important issues to watch moving forward, as they could curtail the import of *Escobar* to the detriment of healthcare providers. For instance, in *U.S. ex rel. Dresser v. Qualum Corp.* the district court rejected the government’s implied certification claim because the government failed to satisfy *Escobar*’s materiality standard by generally alleging that it would not have paid defendants’ claims had it known of the alleged noncompliance with Medicare staffing regulations.⁶⁹ Yet, the district court allowed the government’s express certification claim to proceed where the defendant certified in a CMS-1500 claim form that it had complied with “all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment.” In the context of this broad express certification, the district court found the materiality requirement satisfied—without explanation—by the government’s conclusory allegation that it would only pay for sleep tests that complied with the Medicare staffing regulations at issue.

Other courts have denied FCA claims based on broad certifications, like the one at issue in *Dresser*, which did not reference compliance with the particular requirement the defendant allegedly violated. In *U.S. ex rel. Bishop v. Wells Fargo & Co.*, the Second Circuit rejected an attempt by relators to premise FCA liability on defendant’s broad certifications in a lending agreement of compliance with “any laws or regulations” that “could have any adverse effect” with the agreement.⁷⁰ To hold otherwise, the Second Circuit explained, would not “sufficiently cabin” the express certification requirement, as the defendant’s banks are “subject to thousands of laws and regulations that could plausibly affect” the terms of the lending agreement.⁷¹ *U.S. ex rel. Tessler v. City of New York* similarly held that a certification of compliance with “applicable implementing” statutes and regulations could not form the basis of an express certification FCA claim because “the representation has to refer to compliance with a particular law.”⁷²

67. 2016 WL 4059667, at *12-13 (E.D. Penn. July 26, 2016).

68. See *U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1174 (10th Cir. 2016) (pre-*Escobar* decision explaining that “[a]lthough express and implied claims differ, both nonetheless share some common elements, including a materiality requirement”); *United States v. Fulton Cnty., Ga.*, 2016 WL 4158392, at *5 (N.D. Ga. Aug. 5, 2016) (post-*Escobar* decision stating that “[t]he misrepresentation, whether express or implied, must be material to the other party’s course of action”).

69. 2016 WL 3880763 (N.D. Cal. July 18, 2016).

70. 823 F.3d 35, 45-46 (2d Cir. 2016).

71. Notably, the Second Circuit distinguished *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010), where the Tenth Circuit found a certification in a payment request that work was performed “in accordance with the specifications, terms and conditions of the contract” to be sufficient, by noting that a contract has limited terms whereas a broad certification with all applicable laws is open-ended.

72. 2016 WL 7335654, at *4 (S.D.N.Y. Dec. 16, 2016).

Objective Falsity in Medical Necessity Cases

Several opinions were issued last year concerning what is required to establish falsity in FCA cases premised on allegations of medically unnecessary care. Such cases often center on a battle of medical experts, with the parties disputing whether proof exists of an objective falsehood and/or whether objective falsity is a prerequisite to FCA liability.

Two noteworthy cases, *U.S. ex rel. Paradies v. AseraCare, Inc.* and *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, involved allegations that hospice providers submitted false claims to Medicare by certifying patients as eligible for hospice who did not have a prognosis of six months or less to live if their illness ran its normal course.⁷³ In both cases, the respective district courts granted summary judgment for the defendant hospice provider on the issue of falsity, *i.e.*, whether the patients at issue were terminally ill and eligible for hospice care. In so ruling, the district courts explained that the government (in *AseraCare*) and relator (in *Wall*) failed to point to any objective evidence of falsity and instead relied solely on subjective clinical analysis.

The district court's opinion in *AseraCare* emphasized that the government did not challenge the existence of a physician's certification of terminal illness for the claims at issue and did not identify any evidence that the certifying physician relied on any false or incorrect information or that clinicians withheld information from the certifying physicians. Absent such allegations, the district court ruled that the government's case rested on a "contradiction based on clinical judgment or opinion" that "alone cannot constitute falsity under the FCA as a matter of law."

The district court's opinion in *AseraCare* is currently on appeal before the Eleventh Circuit and will be an important case to watch in 2017 regarding the need to identify objective falsity in FCA cases premised on the question of medical necessity.⁷⁴

Similarly, in *Wall*, the district court noted that if the relator had put forth evidence that a physician certified eligibility despite never actually seeing the patient or that a physician did not actually believe the patient had less than six months to live when certifying otherwise, such evidence could establish liability, but that "an FCA claim about the exercise of [clinical] judgment" cannot rest on "questioning subjective

"[R]elators may not be in a position to see the entire picture or may simply have a subjective disagreement with the other party on the most prudent course of action. Further, their perspective may be colored by considerable bias or self-interest, such as in the case of a disgruntled employee. The heightened possibility of mistake or bias supports the need for a higher standard of specificity for fraud compared to other civil litigation."

-U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC

clinical analysis;" instead, the relator must identify "objectively verifiable fact[s] at odds with the exercise of that judgment."

Notably, the district court in *Wall* also found that defendants' "aggressive marketing and enrollment policies" were "not sufficient to prove falsity," when relator failed to establish any "causal link" between defendants' "policies, a few instances where medical information was allegedly falsified, and actual false or fraudulent certifications and claims."⁷⁵

Outside the hospice context, in *U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC*, the relator alleged that a mental health clinic fraudulently billed for medically unnecessary services related to urine screens and patient visits for medications as a result of certain company policies. The Seventh Circuit affirmed the dismissal of the majority of the allegations because the relator failed to provide "medical, technical, or scientific context which would enable a reader of the complaint to understand why [the defendants'] alleged actions amount to unnecessary care forbidden" by the relevant Medicare statute.⁷⁶ The Seventh Circuit explained that "Acacia's policies could have entirely innocent explanations" and relator's failure to plead "a concrete basis" "to question the appropriateness of these policies" (e.g., how Acacia's policies compare to other clinics) was fatal to its complaint. Furthermore, the complaint's reliance on relator's "personal estimation" was deemed insufficient to establish

73. *AseraCare*, 2016 WL 1270521 (N.D. Ala. Mar. 31, 2016); *Wall*, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

74. The district court's summary judgment opinion followed an unusual procedural trajectory. In 2015, this case proceeded to a bifurcated trial, with the issue of falsity tried first and with the government permitted to use statistical sampling and extrapolation. After the jury returned a verdict finding *AseraCare* had submitted false claims for 104 of the 123 patients in the sample, the district court vacated the jury verdict and reopened the question of whether summary judgment should be entered, noting that it had "committed reversible error in failing to provide the jury with complete instructions as to what was legally necessary for it to find that the claims before it were false." 2015 WL 8486874 (N.D. Ala. Nov. 3, 2015).

75. See also *AseraCare*, 2016 WL 1270521, at *4-5 (N.D. Ala. Mar. 31, 2016) ("[P]ractices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare.").

76. 836 F.3d 770 (7th Cir. 2016).

falsity considering that “relators may not be in a position to see the entire picture” and “their perspective may be colored by considerable bias or self-interest.” The Seventh Circuit concluded that relator’s “subjective evaluation, standing alone, is not a sufficient basis for a fraud claim.”

However, in **U.S. ex rel. Hayward v. SavaSeniorCare, Inc.**, where the government has alleged that a SNF operator billed Medicare for medically unnecessary skilled therapy, the district court observed that while “[m]any cases hold that objective falsity is a prerequisite to FCA liability,” one case had held that “proof of an objective falsehood is not the only means of establishing an FCA claim,” and in two other cases, courts were not willing to “automatically exclude” FCA liability when facts relied upon clinical judgment.⁷⁷ The district court, in denying the defendants’ motion to dismiss, did little to explain why objective falsity was not required in this instance, beyond generally stating that the district court’s “present concern is not what must be proven, but rather what must be pled.” The district court found “the essence of the claims [to be] the same” as those in **U.S. ex rel. Martin v. Life Care Centers of America, Inc.**, where the district court denied a motion to dismiss the government’s allegations against a SNF operator.⁷⁸ It reached this conclusion even though the district court acknowledged that, unlike in **Life Care**, the government’s complaint did not reference the patient exemplars’ “clinical characteristics” or allege that the patient exemplars “could not reasonably be expected to participate in certain [therapy] activities.”

“Where the nature of the claim requires an individualized determination, that determination cannot be replaced by Trial by Formula.”

-U.S. ex rel. Wall v. Vista Hospice Care, Inc.

Use of Statistical Sampling to Establish Falsity

In previous years, we have covered in depth the use of statistical sampling to establish FCA liability across a broad universe of claims. Last year, in **Wall**, the district court concluded that such extrapolation was impermissible. The district court reached that

conclusion in connection with granting the defendants’ motion to strike relator’s statistical expert, who extrapolated from a physician’s testimony regarding the hospice eligibility of a patient sample to conclude that defendants had submitted false claims on approximately 12,000 patients. The district court explained that each hospice claim is uniquely fact-dependent, implicating “different patients, different medical conditions, different caregivers, different facilities, different time periods, and different physicians,” and is based on prognostication, which is inherently uncertain. Citing to a recent Supreme Court decision,⁷⁹ the district court noted that “[w]here the nature of the claim requires an individualized determination, that determination cannot be replaced by ‘Trial by Formula.’” The district court concluded that, while there are circumstances where statistical sampling may be appropriate, the diversity of claims rendered proof of liability through statistical sampling evidence inappropriate.

As we covered last year, no appellate court has resolved whether statistical sampling and extrapolation can be used to establish liability in an FCA case. The issue was certified for interlocutory appeal to the Fourth Circuit in **U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.**, a non-intervened FCA case involving the medical necessity of certain services furnished to nursing home patients.⁸⁰ Oral argument was held in this matter in October 2016, so a decision is likely in 2017. Based on the questions posed during oral argument, however, it appears likely that the Fourth Circuit will avoid the question of statistical sampling by focusing solely on the question of the government’s right to object to a settlement reached between a relator and a defendant in a declined *qui tam* action—a separate issue also certified for interlocutory appeal.⁸¹ Healthcare providers should closely watch for a decision in this matter in 2017.

Health Information Technology for Economic and Clinical Health (HITECH)

In **U.S. ex rel. Sheldon v. Kettering Health Network**, the Sixth Circuit was the first appellate court to consider and reject FCA liability based on a healthcare provider’s alleged false attestation of compliance with the Health Information Technology for Economic and Clinical Health (HITECH) Act’s meaningful use objectives.⁸² In **Sheldon**, the relator alleged that Kettering did not meet the HITECH Act’s meaningful

77. 2016 WL 5395949, at *13 (M.D. Tenn. Sept. 27, 2016).

78. See **U.S. ex rel. Martin v. Life Care Centers of America, Inc.**, No. 08-251, Dkt. No. 106 (E.D. Tenn.).

79. **Wal-Mart Stores, Inc. v. Dukes**, 564 U.S. 338, 367 (2011).

80. No. 15-238 (4th Cir.); see also **Agape**, 2015 WL 3903695 (D.S.C. July 6, 2015).

81. See <http://www.insidethefca.com/2016/10/matt-curley-analyzes-oral-arguments-in-fourth-circuit-agape-case>.

82. 816 F.3d 399 (6th Cir. 2016).

use objectives and compliance measures due to (1) isolated medical record breaches and (2) Kettering's failure to run "CLARITY" reports from its software system to assist in monitoring improper medical record access. As a result, the relator claimed that Kettering's meaningful use attestation was false, leading it to receive improper meaningful use incentive payments.

The Sixth Circuit held that: (1) an "attestation of compliance [with the HITECH Act] is not rendered false by virtue of individual breaches;" (2) allegations of occasional breaches of EHR, without more, cannot support an inference that a provider lacked policies and procedures necessary for HITECH Act compliance (and in fact the complaint's allegations referenced the existence of such policies); and (3) HITECH Act compliance does not "require that providers adhere to a particular schedule for running [CLARITY] reports, or to purchase and use a particular brand of EHR software."

"[A]n FCA defendant's reasonable interpretation of an ambiguous regulation belies the scienter necessary to establish a claim of fraud under the FCA."

-U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC

Developments Regarding Knowledge/Scienter

To prevail in FCA cases, relators or the government must prove that the defendant acted with the requisite level of knowledge in connection with the FCA allegations at issue. In a number of cases, defendants made considerable headway in convincing courts to scrutinize allegations of knowledge closely, particularly in instances where defendants argued that the underlying conduct at issue was governed by ambiguous statutes or regulations.

In ***U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC***, the Eighth Circuit affirmed summary judgment for Anesthesia Assocs. of Kansas City (AAKC), finding AAKC's objectively reasonable interpretation of an ambiguous regulation precluded a determination that AAKC knowingly submitting false

claims in violation of the FCA.⁸³ This holding "lies in harmony with the principle that summary judgment is not proper on the issue of FCA scienter *if* a Relator (or the United States) produces sufficient evidence of government guidance that warned a regulated defendant away from an otherwise reasonable interpretation of an ambiguous regulation."⁸⁴ In this case, the relator failed to submit evidence refuting AAKC's strong showing that its interpretation of the provision was objectively reasonable or demonstrating that the government had warned AAKC of a different interpretation. The Eighth Circuit disagreed that AAKC had a duty to confirm that its interpretation was proper, noting "[a]s the agency had not clarified an obvious ambiguity in [the provision at issue] for decades, AAKC's failure to obtain a legal opinion or prior CMS approval cannot support a finding of [scienter]."⁸⁵

The Eighth Circuit ruled similarly in ***U.S. ex rel. Olson v. Fairview Health***, affirming dismissal of a complaint based on the relator's inability to assail the defendant hospital's "reasonable interpretation of ambiguous statutory language" and thus adequately plead scienter.⁸⁶ The relator argued that the statute at issue was unambiguous and the defendants' interpretation of "children's hospital" to include its children's unit was unreasonable, but in so doing, relied heavily on his role in drafting the applicable statutory language and the historical and contextual understanding of "children's hospital" in Minnesota. The Eighth Circuit noted that legislative history is properly consulted only for textual ambiguities, thus the relator's support "actually favor[ed] a finding that [defendant] did not act fraudulently."⁸⁷

In ***U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.***, the Sixth Circuit was the first circuit to interpret the FCA's scienter requirement in relation to the post-FERA versions of the reverse false claims and conversion provisions.⁸⁸ The relators alleged that Muskingum Watershed Conservancy District (MWCD) knowingly withheld United States property from the federal government after it violated certain deed restrictions that triggered a provision reverting ownership in the land to the United States. The Sixth Circuit held that the term "knowingly" must be interpreted to refer to MWCD's awareness of both the existence of a relevant obligation and the defendant's own avoidance of that obligation. The Sixth Circuit affirmed dismissal under Rule 8(a), finding that the relators had failed to state facts

83. 833 F.3d 874 (8th Cir. 2016).

84. *Id.* at 879 (quotations and citation omitted).

85. *Id.* at 880 (quotations and citation omitted).

86. 831 F.3d 1063 (8th Cir. 2016).

87. *Id.* at 1072.

88. 842 F.3d 430 (6th Cir. 2016).

from which MWCD's awareness of the FCA violations could be inferred, even under the relatively liberal standard of Rule 8(a).

In ***U.S. ex rel. Miller v. Weston Educ., Inc.***, the Eighth Circuit reversed summary judgment for the defendants on the issues of knowledge and materiality.⁸⁹ Relators alleged that defendant Heritage College fraudulently induced the Department of Education to provide funds by falsely promising in its Program Participation Agreement (PPA) to keep accurate student records. The Eighth Circuit focused on Heritage's pre-PPA knowledge and intent to determine whether, when signing the PPA, Heritage knew accurate grade and attendance records were required and intended not to maintain those records. Based on evidence that Heritage: (1) had its own policy acknowledging the vital importance of accurate student records; (2) was aware from the PPA and other sources that accurate records were necessary to ensure proper and efficient administration of funds; (3) had a pattern of altering records, both before and after signing the PPA; and (4) aimed to maximize Title IV funds, the Eighth Circuit found that a dispute of material fact existed as to whether Heritage intended to manipulate its records at the time it signed the PPA and summary judgment was inappropriate. The case was remanded by the Eighth Circuit for further proceedings before the district court.

In ***U.S. ex rel. Swoben v. United Healthcare Ins. Co.***, the relator alleged that defendant Medicare Advantage organizations took affirmative steps to generate and report skewed data in order to increase capitated payments from CMS, rendering their certifications of accurate data false.⁹⁰ The relator alleged the defendants knew their certifications were false because they: (1) helped design a template that would not capture disadvantageous errors; (2) were on notice from risk adjustment data validation (RADV) audits that their reported data had a 20% error rate; and (3) designed retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted codes that might have otherwise been identified with the diligence required by the applicable regulations. The Ninth Circuit rejected the defendants' argument that their conduct represented an objectively reasonable interpretation of their diligence obligations and noted the defendants did not need actual knowledge of any specific unsupported diagnosis codes for a jury to find the requisite scienter. After finding the district court abused

its discretion in denying leave to file a fourth amended complaint, the Ninth Circuit remanded for further proceedings.

In ***U.S. ex rel. Sheet Metal Workers Int'l Assoc. v. Horning Inv., LLC***, the Seventh Circuit affirmed summary judgment for the defendant. The relator alleged that the defendant knowingly submitted false statements to the government certifying that it was paying Davis-Bacon rates to employees.⁹¹ The Seventh Circuit found that there was "enough ambiguity" about the circumstances of calculating and accounting for fringe benefits in wage reports "that we cannot infer that Horning either knew or must have known it was violating the Davis-Bacon Act."⁹² Further, the Seventh Circuit noted in dicta that "[i]n some situations, reliance on the advice of a professional, such as an attorney or an accountant, can negate the mental state" required to find an FCA violation, but found Horning had not developed the facts needed to provide a basis for such defense in the present case.

Finally, in ***U.S. ex rel. Polansky v. Exec. Health Res.***, the district court denied dismissal of allegations that defendant EHR participated in a nationwide and nearly decade-long scheme to cause client hospitals to knowingly bill patient admissions as inpatient when they should have properly been billed as outpatient services.⁹³ EHR completed second level medical necessity review for client hospitals. The relator argued that "the gap between EHR's approach to second level review and the applicable legal requirements is so enormous, that the only plausible explanation ... is that EHR knowingly ignored them ... to devise a review platform that would generate vast numbers of false inpatient status certifications."⁹⁴ The district court agreed that the relator had adequately pleaded scienter, noting that the relator provided specific examples of EHR's awareness of how its approach differed from the applicable regulatory framework, including internal discussions among leadership about CMS guidance and inclusion of CMS guidance in promotional materials.

REVERSE FALSE CLAIMS

On February 11, 2016, CMS published a final rule on the reporting and return of overpayments within 60 days; an obligation commonly known as the "60-day rule." The final CMS rule, which relates to Medicare Part A and Part B only, eases

89. 840 F.3d 494 (8th Cir. 2016).

90. 832 F.3d 1084 (9th Cir. 2016).

91. 828 F.3d 587 (7th Cir. 2016).

92. *Id.* at 594.

93. 2016 WL 4059667 (E.D. Pa. July 26, 2016).

94. *Id.* at *19.

some of the requirements for healthcare providers and suppliers compared to what CMS originally proposed four years ago.⁹⁵ However, given that the failure to timely report an overpayment can lead to FCA exposure, the final rule has significant FCA implications for healthcare providers.

Under the “reverse false claim” provision of the FCA, 31 U.S.C. § 3729(a)(1)(G), liability may arise when a provider or supplier “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” An “obligation” includes the retention of any overpayment.⁹⁶ And, PPACA explicitly states that the 60-day rule is an “obligation” for purposes of the FCA.⁹⁷

CMS clarified that an overpayment is “identified” when “the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment” with a reasonable degree of certainty.⁹⁸ CMS noted in its final rule that “reasonable diligence” requires “proactive compliance activities” and investigations to uncover potential overpayments.⁹⁹ The proposed rule contained a narrower definition that mirrored the FCA’s knowledge standard, stating that an overpayment was identified when a person had “actual knowledge” of the overpayment or acted in “reckless disregard or deliberate ignorance” of its existence.¹⁰⁰ The final rule seemingly expands the definition of “identified” to include acts that may not rise to the level of fraud subject to FCA liability.

CMS’ final rule also stands in contrast to the momentous district court decision in ***U.S. ex rel. Kane v. Healthfirst, Inc.***, which provided the first judicial interpretation of the meaning of “identified” within PPACA’s 60-day rule.¹⁰¹ In ***Kane***, the district court held that “identified” means that “the sixty day clock begins ticking when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained.”¹⁰² The district court explicitly rejected the defendant’s argument the 60-day time period was not triggered until the overpayments had been confirmed and quantified—which is now the rule for

Medicare Part A and Part B claims.¹⁰³

Because the overpayments in ***Kane*** were made by Medicaid, not Medicare, the district court’s interpretation of “identified” may continue to influence FCA reverse false claims liability in regards to Medicaid. Six months after CMS published the final rule, the parties reached a settlement regarding the allegations of delayed Medicaid repayments for \$2.95 million, an amount nearly 3.5 times the improper billing amount stipulated in the settlement documents.

The Eighth Circuit held, in ***U.S. ex rel. Olson v. Fairview Health Services of Minnesota***, that the relator failed to show the hospital knew it had an obligation to the government, as it had relied on a reasonable interpretation of an ambiguous state statute when it retained government payments.¹⁰⁴ Further, this decision went against the recent trend of relaxed pleading standards by applying the heightened standard to whether the relator sufficiently alleged the defendant acted knowingly. The dissent agreed that a defendant acts without knowledge when his interpretation of an applicable law is a reasonable one, but questioned whether “subsection (a)(1)(G) requires some sort of ‘fraudulent conduct’ that necessarily implicates the requirement that fraud be pled with particularity.”¹⁰⁵

THE FCA’S PUBLIC DISCLOSURE BAR

The FCA’s public disclosure bar prevents a relator from filing a *qui tam* complaint based on information previously disclosed to the public, thereby dissuading parasitic lawsuits based on publicly available information. Courts in previous years spent significant time addressing the effects of PPACA’s amendments to the FCA. As those issues continue to gain clarity, cases analyzing the public disclosure bar from last year focused primarily on what disclosures are sufficient to trigger the bar and how a relator can qualify for the “original source” exception to the public disclosure bar under the statute.

95. 81 Fed. Reg. 1128J(d).

96. *Id.* at 7659.

97. 42 U.S.C. § 1320a-7(k)(d)(3).

98. 81 Fed. Reg. at 7662.

99. *Id.* at 7664.

100. *Id.* at 7659.

101. 120 F. Supp. 3d 370 (S.D.N.Y. 2015).

102. *Id.* at *11.

103. Mem. in Support of Defs.’ Mot. to Dismiss, No. 11-cv-2325 (S.D.N.Y. Sept. 22, 2014), Doc. No. 55, at p. 1.

104. *U.S. ex rel. Olson v. Fairview Health Services of Minnesota*, 831 F.3d 1063 (8th Cir. 2016).

105. *Id.* at 1075.

Whether the Public Disclosure Bar Remains Jurisdictional

Continuing a trend from previous years, the Sixth Circuit joined a growing group of federal appellate courts to hold that the public disclosure bar is no longer jurisdictional after the 2010 PPACA amendments. In ***U.S. ex rel. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A.***, the Sixth Circuit cited Supreme Court precedent for the principal that “[u]nless Congress has ‘clearly state[d]’ that a rule is jurisdictional ... courts should treat the restriction as nonjurisdictional in character.”¹⁰⁶ The Sixth Circuit reasoned that the public disclosure bar is no longer jurisdictional because Congress removed the jurisdictional language through PPACA’s amendments to the FCA. The Sixth Circuit noted that every other circuit to address this question of jurisdiction has reached the same conclusion.¹⁰⁷

When Are Disclosures Sufficient to Bar FCA Allegations?

Courts last year provided some additional guidance in determining whether generalized public allegations of fraud are substantially similar enough to bar subsequent suits, how the source and accessibility of the relevant disclosures affects the public disclosure analysis and how to apply the so-called last pleading rule to the public disclosure bar.

To determine whether previous public disclosures are sufficiently similar to allegations of fraud to trigger the public disclosure bar, both the Seventh and Ninth Circuits have now adopted what they call a “level of generality” test, determining that they must compare similar allegations at a “low” level of generality. Under that test, a court must compare the granular, specific allegations and schemes in the *qui tam* suit to the broader allegations in the public domain to see if the suit is different “in kind or degree” before barring the subsequent suit.

In ***U.S. ex rel. Mateski v. Raytheon***, the relator alleged that Raytheon violated the FCA by failing to comply with numerous contractual requirements in the development of a satellite system for the government.¹⁰⁸ Before the complaint was filed, several government agencies issued reports that generally claimed mismanagement, inadequate oversight and technical challenges by Raytheon. The Ninth Circuit found

that while the government reports and accompanying news coverage described a “transaction” of fraud, or facts from which fraud could be inferred, the relator’s complaint was not “substantially similar” to those publicly disclosed facts. In reaching that conclusion, the Ninth Circuit adopted the Seventh Circuit’s “level of generality” test, which allows FCA suits to continue where they rest on “genuinely new and material information.”¹⁰⁹ According to the Ninth Circuit, holding otherwise would allow a public document describing “problems” or even some generalized reference to or allegations of fraud to bar all FCA suits identifying specific instances of fraud. The Ninth Circuit held that the relator’s allegations were different “in kind and in degree” from previously disclosed facts and, therefore, must be allowed to move forward.

Where a relator merely adds additional parties or locations to previously disclosed fraudulent schemes, however, the public disclosure bar likely applies. In ***U.S. ex rel. Winkelman v. CVS***, the First Circuit affirmed dismissal of claims where the fraudulent practice alleged had been the subject of significant media coverage and was investigated specifically by the Attorney General of Connecticut. The First Circuit held that, while the previous investigation related substantially to the Connecticut Medicaid program, the related disclosures contained the “essential elements” of the fraud, and mere application of those elements to similar programs across the United States in the complaint was insufficient to avoid the public disclosure bar.¹¹⁰ Other courts similarly have found that adding details that could be derived from, but did not actually appear in, publicly disclosed allegations is insufficient to avoid the bar,¹¹¹ including allegations that previously disclosed fraud simply was ongoing or continued into the present.¹¹²

The source of publicly disclosed information continues to remain significant to the public disclosure analysis. In ***U.S. ex rel. May v. Purdue Pharma***, the Fourth Circuit held that the relators could not use facts learned by their attorney in a previous case to defeat the public disclosure bar.¹¹³ The Fourth Circuit held that a complaint is barred where it is “based upon” the previous work done by the relators’ attorney relating to a previously dismissed and publicly disclosed *qui tam* suit involving the

106. 816 F.3d 428, 433 (6th Cir. 2016) (quoting *Sebellius v. Auburn Reg’l Med. Ctr.*, 133 S. Ct. 817, 824 (2013)).

107. *See id.* (collecting cases).

108. 816 F.3d 565, 568 (9th Cir. 2016).

109. A suit by long term executives at the defendant company similarly was barred, as relators described the same fraudulent scheme as a previously filed and unsealed *qui tam* suit. *See U.S. ex rel. Conroy v. Select Medical*, 2016 WL 5661566 (S.D. Ind. Sept. 30, 2016). The district court found that the relators “merely add to the outline of fraudulent conduct previously disclosed in the public domain” and do not add “genuinely new or material information” to the scheme.

110. 827 F.3d 201 (1st Cir. 2016).

111. In *U.S. ex rel. Lager v. CSL Behring*, 158 F. Supp. 3d 782, 791 (E.D. Mo. 2016), the district court held that the addition of the actual sales price of certain drugs that the relator argued was being artificially inflated by the manufacturer was insufficient to overcome the bar when the government could have deduced that information from the publicly available facts.

112. In *U.S. ex rel. Hirt v. Walgreens*, 2016 WL 1367182 (M.D. Tenn. Apr. 5, 2016), the district court barred a jurisdictional suit that was “essentially identical” to a previous *qui tam* suit and DOJ press release, but alleged that the practice continued after these settlements. A suit is barred where it is, even in part, based on the allegations in the publicly disclosed allegations.

113. 811 F.3d 636, 641 (4th Cir. 2016).

same underlying alleged fraud. The Fourth Circuit held that the relators did not learn of the alleged fraud independently from the prior lawsuit; their knowledge stemmed from their attorney's involvement in the prior action, and his knowledge was imputed to them.

Similarly, the U.S. District Court for the District of New Jersey dismissed another "second-hand" lawsuit in *U.S. ex rel. Silver v. Omnicare*, where the relator was the former owner of a nursing home and a pharmacy but never had worked for or done any business with the defendant.¹¹⁴ The relator derived his allegations almost entirely from HHS-OIG reports, financial statements of the company and interviews with several individuals. The district court held that even if the relator had discovered some non-public information relating to allegedly fraudulent activities, that could not save the complaint, as the public disclosure bar applies to actions even partly based on public disclosures.

Courts last year also analyzed the degree of "publicity" that is required for information to constitute a "public" disclosure for purposes of the bar. In *U.S. ex rel. Oliver v. Philip Morris*, the D.C. Circuit held that a memorandum and some contracts clauses that were among almost five million other documents published by Philip Morris on a court-mandated website were sufficient.¹¹⁵ The D.C. Circuit held that the standard for disclosure is whether the document is "actually available" as opposed to "reasonably likely to be discovered." Similarly, the Third Circuit held that information disclosed through a Freedom of Information Act (FOIA) request is considered a "report" sufficient to trigger the public disclosure bar.¹¹⁶

Finally, the Fourth Circuit applied a more nuanced version of the Supreme Court's last pleading rule to a third amended complaint in *U.S. ex rel. Beauchamp v. Academi Training Center*.¹¹⁷ The Fourth Circuit held that only public disclosures that exist when the relator initially pleads the alleged fraudulent scheme are relevant to the public disclosure analysis; later disclosures that exist when a subsequent amended complaint is filed are not relevant. In *Beauchamp*, one year after the relators filed their *qui tam* complaint, a public retaliation lawsuit filed against the same defendant

and an article published on the internet disclosed facts related to some of the allegations in the relators' FCA suit. The relators subsequently amended their *qui tam* complaint with information from that article and the retaliation lawsuit. The Fourth Circuit held that the relators had "particularly alleged" the fraudulent scheme in their original complaint before the retaliation suit was filed and the article was published. Although the relators added significant detail to the amended complaint, the operative date for the purposes of the public disclosure bar analysis was the date on which the scheme originally was pleaded.¹¹⁸

When Is a Relator an Original Source?

The requirements for a relator to be considered an original source and thereby exempted from the FCA's public disclosure bar remained a significant issue. Although courts in previous years grappled with whether to apply the pre-PPACA or post-PPACA version of the statute to the allegations at hand, courts increasingly conduct the original source analysis under the post-PPACA version of the statute as allegations become less likely to pre-date 2010. Thus, courts most frequently analyze whether a relator has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," as defined in the post-PPACA version of the FCA, though interpretations of that requirement continue to vary.

The Seventh Circuit applied a rather narrow interpretation of the original source definition in *U.S. ex rel. Bogina v. Medline Industries, Inc.*¹¹⁹ Although the allegations pre-dated the 2010 PPACA amendments, the Seventh Circuit applied the post-PPACA definition of "original source," reasoning "that because the earlier definition is inscrutable as well as skimpier than the current one, the current one should be deemed authoritative regardless of when a person claiming to be an original source acquired his knowledge."¹²⁰ Applying the post-PPACA definition, the Seventh Circuit determined that the relator was not an original source because "he merely 'add[ed] details' to what [was] already known in outline" from a different, previous lawsuit against the same defendant.¹²¹ The relator's allegations focused on

114. 2016 WL 6997010 (D.N.J. Nov. 28, 2016).

115. 826 F.3d 466, 475 (D.C. Cir. 2016).

116. *U.S. ex rel. Moore v. Majestic Blue*, 812 F.3d 294 (3d Cir. 2016). The relators alleged that the defendants had falsely certified that certain fishing vessels were managed and commanded by United States citizens when they were actually controlled and commanded by non-citizens. The Third Circuit found that the public disclosure bar applied where these facts were disclosed through news media articles in conjunction with emails and certifications of compliance obtained through FOIA requests. The Third Circuit held that FOIA responses, and the accompanying documents, are "reports" both before and after the amendments to the FCA.

117. 816 F.3d 37, 44 (4th Cir. 2016) (citing *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007) (holding that the public disclosure bar applies to "the allegations in the original complaint as amended").

118. Applying this same test a few months later, but not citing to any precedent, the U.S. District Court for the Eastern District of New York held that claims against two individually named defendants were barred where they were added in an amended complaint following their criminal indictments for the alleged conduct. See *U.S. ex rel. Keshner v. Immediate Home Care*, 2016 WL 354599 (E.D.N.Y. June 24, 2016). The district court allowed allegations against the corporate defendant to continue where those allegations were pleaded in the original complaint, prior to the public disclosures.

119. 809 F.3d 365, 368 (7th Cir. 2016).

120. *Id.* at 368.

121. *Id.* at 370.

different customers, different government healthcare programs and a different time period – alleging that the fraud was “continuing” – than did the previous lawsuit. Nonetheless, the Seventh Circuit deemed those differences “unimpressive” and held that they did not “materially add” to what had been disclosed in the previous action and that the government “was on notice of the possibility of a broader bribe-kickback scheme before [the relator] sued.”¹²²

In *Winkelman*, the First Circuit analyzed the meaning of the “materially adds” language of the original source exception as a matter of first impression. Citing *Escobar*, the First Circuit stated that “material” information in this context is a “narrow category of information” that must be “sufficiently important to influence the behavior of the recipient.”¹²³ It observed that “[a]s the level of detail in public disclosures increases, the universe of potentially material additions shrinks.”¹²⁴ Like the Seventh Circuit in *Bogina*, the First Circuit held that allegations that the fraud was occurring in additional states, under additional government healthcare programs, and on an ongoing basis did not materially add to previously disclosed information.¹²⁵ The Seventh Circuit did not foreclose the possibility that furnishing information that a defendant acted “knowingly” could suffice as a material addition, but in this case the public disclosures already illustrated that the defendant acted deliberately.¹²⁶

The Third Circuit took a broader view of the “original source” definition in *Moore & Co.*¹²⁷ The Third Circuit observed that the PPACA amendments to the FCA’s original source definition was part of a “radical change” to the public disclosure bar and that amended language “evinces Congress’s intent to lower the bar for relators.”¹²⁸ The relator in that case obtained information through discovery in a separate wrongful death action. The Third Circuit held that such information constituted “independent” knowledge of the alleged fraud, concluding that because the relator “discovered information such as what specific individuals were involved in the alleged fraud and how they initiated and perpetrated the alleged transgression,” the relator “added to the publicly disclosed information in a material way.”¹²⁹

The Seventh Circuit focused its original source analysis primarily on the requirement that a relator’s knowledge be “independent” in *Cause of Action v. Chicago Transit Authority*.¹³⁰ Applying the post-PPACA version of the statute but citing pre-PPACA authority – both versions of the statute contain the “independent” requirement – the Seventh Circuit held that to qualify as an original source, the relator must be “someone who would have learned of the allegation or transactions independently of the public disclosure.”¹³¹ Because the relator did not learn of the alleged fraud until it reviewed reports that constituted public disclosures, and because there was “no reason to believe that [the relator] would have ever learned of the wrongdoing” without the disclosures, the relator lacked “independent” knowledge of the alleged fraud.¹³² The Seventh Circuit also noted that the relator did not materially add to the public disclosure because its allegations were “substantially similar to those contained in” the reports.¹³³

Some courts interpreting the pre-PPACA original source definition focused on whether the relator possessed firsthand knowledge of the alleged fraud. In *Oliver*, a case originally filed in 2008, the D.C. Circuit acknowledged that a relator need not possess “direct and independent” knowledge about each component of the fraudulent transaction but that knowledge about “any essential element of the underlying fraud transaction” suffices.¹³⁴ Nevertheless, the D.C. Circuit held that the relator lacked “direct” information of the alleged fraud because he possessed no firsthand knowledge of the alleged improper price differential but instead gained all of his knowledge secondhand. Although the relator investigated the allegedly improper conduct before filing his complaint, he had no firsthand knowledge that led him to believe that fraud had been committed; his belief was based on the knowledge and information of other people and was, therefore, secondhand and not “direct” for purposes of the original source analysis.

Similarly, in *U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings*, the Eleventh Circuit held that the relator’s secondhand knowledge was insufficient to make him

122. *Id.* at 369–70.

123. *Winkelman*, 827 F.3d at 211.

124. *Id.*

125. *Id.* at 212–13.

126. *Id.* at 213.

127. 812 F.3d at 304.

128. *Id.* at 298–99.

129. *Id.* at 307, 308.

130. 815 F.3d 267, 282–83 (7th Cir. 2016).

131. *Id.* at 283 (quoting *United States v. Bank of Farmington*, 166 F.3d 853, 865 (7th Cir. 1999), overruled by *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009)).

132. *Id.* at 283.

133. *Id.*

134. *Oliver*, 826 F.3d at 476.

an original source.¹³⁵ Although it acknowledged that the relator had firsthand, direct and independent knowledge about the defendant's administration of overfill drugs, the Eleventh Circuit held that firsthand knowledge about improper billing – the basis of the false claims allegation – was required for the relator to be an original source. The relator, however, had only heard about the alleged improper billing practices from other people; the Eleventh Circuit held that such secondhand knowledge "is on its face indirect."¹³⁶

DEVELOPMENTS REGARDING DAMAGES AND PENALTIES

For providers facing potential FCA liability, the potential scope of exposure will continue to expand, whether driven by a nearly doubled increase in the penalties recoverable under the FCA, large negotiated settlements backed-up by statistical extrapolation of false claims or the significant increase in relator-driven litigation in government-declined cases. Questions regarding the manner in which FCA damages should be calculated also are likely to persist.

Substantial Penalty Increase

Effective August 1, 2016, penalties under the FCA nearly doubled.¹³⁷ Penalties for each false claim in the range of \$5,500 to \$11,000 per claim were more than doubled to a minimum of \$10,781 up to \$21,563 per claim. The increase applies to penalties imposed pursuant to the FCA for conduct occurring after November 1, 2016. When applying penalties in FCA cases, courts have the discretion to do so within the penalty range provided, but do not have the discretion to impose penalties below or above the range. Ordinarily, penalties are assigned to each false claim submission to the government, potentially generating enormous liability well in excess of actual damages being asserted by the government or a relator.

Civil penalties were last adjusted under the Inflation Adjustment Act of 1996, and were increased by the Bipartisan Budget Act of 2015 (Budget Act) passed in November 2015, designed to "catch up" penalties and adjust for inflation. The Budget Act also required federal agencies to make annual adjustments to penalties in future years and removed a provision from the earlier Inflation Adjustment Act that limited any increase in monetary penalties to 10%. Because the Budget Act also applied the penalty increase to those penalties imposed under the Social Security Act, CMPs also have been increased.

Given that the previous maximum FCA penalty (\$11,000) is now the approximate floor (\$10,781), the increase is expected to have a significant impact on settlement and litigation strategy for FCA defendants. Furthermore, the dramatic increase – combined with subsequent annual increases – will continue to fuel debates about FCA defendants' rights under the Eighth Amendment's Excessive Fines Clause where cumulative penalties resulting from the number of claims substantially outweigh the government's demonstrated actual damages.

Calculating Damages

The method of calculating damages under the FCA continues to be an issue taken up by courts – whether cases involving actual damages directly attributable to the alleged falsity or whether cases involving claims "tainted" by falsity but which may have no correlation to the value of the service or benefit ultimately provided to the government.

Limiting the calculation of damages to the amount directly resulting from the conduct in violation of the FCA was addressed by the Sixth Circuit in *U.S. ex rel. Wall v. Circle C. Construction, LLC*.¹³⁸ In that case, Circle C entered into a contract to construct warehouses at a U.S. Army base. Pursuant to the federal Davis-Bacon Act, Circle C (and its subcontractor) was required to pay its electrical workers a specific wage, and submit a certified payroll. Circle C failed to properly monitor its electrical subcontractor's compliance, and despite its certifications, the subcontractor failed to pay the wages required by the Davis-Bacon Act by \$9,916. As a result, the government claimed that the entire electrical work on the project was tainted by the payroll compliance failure, and asserted damages equal to all payments for the electrical work under the contract in the amount of \$259,298.18, trebled for a total of \$777,894.54, minus \$15,000 already repaid by the subcontractor.

The Sixth Circuit rejected the government's theory, explaining that "actual damages by definition are damages grounded in reality" and are determined by the difference in the value between what the government bargained for and what it received.¹³⁹ The Sixth Circuit reasoned that the government bargained for two things: the buildings to be built, and compliance with the Davis-Bacon Act. The buildings were built and in use, but the government was shorted the payment of compliant wages that should have been paid to electrical workers in the amount of \$9,916, which the Sixth Circuit held was the amount of actual damages. The Sixth Circuit rejected the government's

135. 841 F.3d 927, 935-37 (11th Cir. 2016).

136. *Id.* at 936.

137. Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584.

138. 813 F.3d 616 (6th Cir. 2016).

139. *Id.* at 617-618.

“The damages the government seeks to recover here are fairyland rather than actual.”

-U.S. ex rel. Wall v. Circle C. Construction, LLC

“tainted claims” argument because the shortage in wage payment did not lead to payment for worthless services or goods, noting that the buildings were in use and the lights were on. Nor, as in other cases, was there an “unalterable moral taint” making the goods worthless because no payment of money could compensate the government as a result of the taint. Instead, the Sixth Circuit held that payment of the \$9,916 provided an adequate remedy.¹⁴⁰

The Sixth Circuit’s decision in **Circle C** is similar to its prior consideration of FCA damages in **United States v. United Techs.**, which was another military contract case, where the contractor allegedly made false statements to the government when competing with others to be awarded a contract to build engines for fighter jets.¹⁴¹ In reviewing a substantial damages award to the government by the district court, the Sixth Circuit found that despite the contractor’s misstatements, the government had to show a loss or impact – and remanded for further analysis and consideration of fair market value. The Sixth Circuit stated that when the government gets what it paid for, “it has suffered no actual damages” notwithstanding the fraudulent misstatements.¹⁴² Consequently, the Sixth Circuit rejected the damages award and remanded the case for a determination of whether the government suffered any actual damages by considering evidence of fair market value.

The Sixth Circuit’s ruling in **Circle C** is also consistent with the Seventh Circuit’s decision in **U.S. v. Anchor Mortgage Corp.**, which limited the government’s damages to the “net” damages – providing mitigation equal to the value or benefit the government actually received in calculating damages rather than merely including the entire amount the government paid.¹⁴³

The government’s theory of damages in FCA cases involving “tainted claims”

continues to prevail, however, in matters typically involving healthcare providers. In FCA cases involving tainted claims, the government has argued that claims are tainted and should be included in damages calculations because had the government known of the taint (conduct or misrepresentations), it would not have paid the claims. Many courts have agreed and held that because of the taint, the government did not receive the value it bargained for as a result of the false claims, and would not have paid the claims had it known. If so, the tainted claims are totaled and used to calculate the resulting damages to be trebled and to which the FCA penalty attaches.

The inconsistency in damages theories may be best reflected by comparing the Seventh Circuit’s “net” damages ruling in **Anchor Mortgage** with its earlier decision in **U.S. v. Rogan**.¹⁴⁴ In **Rogan**, the Seventh Circuit agreed that the government’s FCA damages calculations resulting from violations of the AKS and Stark Law consisted of the total amount paid because had the government known about the asserted conduct, it would not have paid the claims at all. Under the government’s theory of damages like that asserted in **Rogan**, the ensuing damages to the government need not stem from any unnecessary, inadequate or worthless service.¹⁴⁵ Rather, because of the defendant’s conduct, the government could not have received the value it had paid to the defendant, and asserted damages as the entirety of the claims paid. Recent cases continue this theory of recovery under the FCA, and FCA cases and settlements reflect this position as the government’s predominate view.¹⁴⁶

DEVELOPMENTS REGARDING RELATORS

Relators’ Conduct

The FCA broadly allows nearly anyone to be a *qui tam* relator, stating “[a] person may bring a civil action for a violation of § 3729 for the person and for the United States Government.” As nothing in the statute precludes attorneys from acting as relators,¹⁴⁷ many attorneys and law firms have brought *qui tam* actions. While acknowledging that the FCA does not preempt state rules on professional responsibility, some courts have allowed attorneys to file *qui tam* actions, even ones against former clients, in furtherance of federal public policy in favor of recovering

140. *Id.*

141. 782 F.3d 718 (6th Cir. 2015).

142. *Id.* at 727.

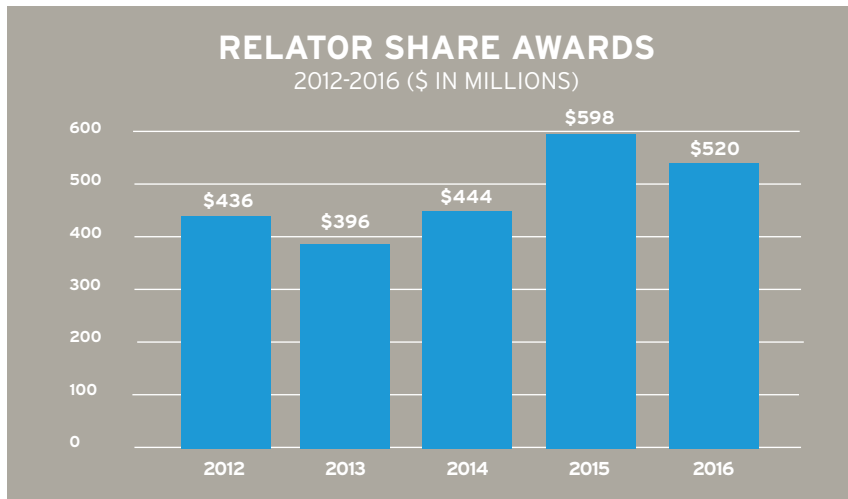
143. 711 F.3d 745 (7th Cir. 2013). *Anchor Mortgage* is cited as authority for the trebling of damages only after determining the net damages, for a “net trebling,” by accounting for any credits, payments or value received prior to the trebling required by the FCA. When determining what damages to treble, the court in *Anchor Mortgage* indicated that “[B]asing damages on net loss is the norm in civil litigation” and “[M]itigation of damages is almost universal.” *Id.* at 749.

144. 517 F.3d 449 (7th Cir. 2008).

145. For example, in *Rogan*, where there was FCA liability as a result of the payment of kickbacks, the court stated that “[n]or do we think it important that most of the patients for which claims were submitted received some medical care – perhaps all the care reflected in the claim forms... [W]hen the conditions are not satisfied, nothing is due.” *Id.* at 453.

146. For example, DOJ announced that it had settled its \$237 million dollar judgment against Tuomey Healthcare System resulting from a jury trial, in exchange for the payment of \$72.4 million by the hospital. The case involved what DOJ referred to as “sweetheart deals” between the hospitals and physicians, and involved more than 21,000 false claims for which penalties were applied. There was no dispute that the services represented by the claims were otherwise properly provided. <http://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital>.

147. 31 U.S.C. § 3730(e)(1) specifically excludes members or former members of the Armed Forces from acting as relators in *qui tam* actions against other members of the Armed Forces arising out of his or her service in the Armed Forces.



the government's fraud-related losses.¹⁴⁸ More recently, however, courts have relied on an attorney-relators' duties of loyalty and confidentiality to clients when disqualifying them from serving as relators, often pointing to the government's ability to maintain the FCA claim after dismissal of the attorney-relator as justification for their decision.¹⁴⁹

In *U.S. ex rel. Holmes v. Northrop Grumman Corp.*, the Fifth Circuit held that the district court did not abuse its discretion when it disqualified an attorney as a relator in an action against a government contractor with whom he had been in foreign arbitration hearings.¹⁵⁰ The attorney relied on documents received under a protective order as the basis for his *qui tam* lawsuit, in clear conflict of interest in regards to his client and in blatant disregard of the court to which he in regards to a duty of candor.¹⁵¹ The Fifth Circuit also explained its dismissal of the relator by stating that the government, the real party in interest in the *qui tam* action, was not barred from pursuing the matter after the disqualification of the relator.¹⁵²

In a non-attorney relator matter, a district court in *U.S. ex rel. Cieszyski v. Lifewatch Services, Inc.*, dismissed a counterclaim by the defendant against the relator, which alleged that the relator's disclosure of conditional information to his attorney and the government amounted to a breach of a confidentiality agreement and privacy policy he had signed in connection with his employment.¹⁵³ In an effort to balance the protection of whistleblowers against employers' interest in protecting their confidential information, the district court analyzed the counterclaim by asking whether the relator's disclosure was more than necessary to pursue his *qui tam* action.¹⁵⁴ Because he did not disclose the information to anyone but the government and his attorney, and did not disclose any attorney-client information or trade secret information, the district court held the relator did not reveal enough to expose himself to a breach of contract action.¹⁵⁵

The Second Circuit, in *U.S. ex rel. Ladas v. Exelis*, rejected the district court's opinion that the government had sufficient knowledge of the allegations of the fraud prior to the release of *qui tam* filing rights, and thus, reversed the district court's holding that the release was enforceable.¹⁵⁶ The Second Circuit held that, as a matter of public policy, a pre-filing release is unenforceable if the government is not informed of the fraudulent allegations prior to its signing.¹⁵⁷

First-to-File

The FCA's first-to-file bar limits the rights of the public to bring an action premised on facts that are already at issue in another pending FCA matter.¹⁵⁸ The parameters of this bar are in dispute amongst the circuits. One such dispute, which was resolved by the Supreme Court last year in *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, involved how a dismissal of a prior suit affects a later-filed action.¹⁵⁹ Some have argued that the bar precludes subsequent litigation even if the previous matter was dismissed.¹⁶⁰ Others argued, as the Supreme Court in *Carter* held, that the bar applies only if the prior matter regarding the same facts is currently pending.¹⁶¹ Once

148. *U.S. ex rel. John Doe v. X Corp.*, 862 F.Supp. 1502 (E.D. Va. 1994); *Erickson v. American Institute of Biological Sciences*, 716 F. Supp. 908 (E.D. Va. 1989).

149. *U.S. ex rel. Fair Lab Practices Assocs. v. Quest Diagnostics Inc.*, 734 F.3d 154 (2nd Cir. 2013).

150. *U.S. ex rel. Holmes v. Northrop Grumman Corp.*, 642 Fed. Appx. 373 (5th Cir. 2016).

151. *Id.* at 377.

152. *Id.*

153. 2016 WL 2771798 (N.D. Ill. May 13, 2016).

154. *Id.* at * 4.

155. *Id.*

156. *U.S. ex rel. Ladas v. Exelis*, 824 F.3d 16 (2d Cir. 2016).

157. *Id.* at 24.

158. 31 U.S.C. § 3730(b)(5).

159. *Kellogg Brown & Root Services, Inc. v. U.S. ex rel. Carter*, 135 S. Ct. 1970 (2015) (holding the *qui tam* action ceases to be pending under the FCA's first-to-file bar once the suit is dismissed).

160. *U.S. ex rel. Shae v. Cellco P'ship*, 2014 WL 1394687 (D.C. Cir. April 11, 2014).

161. See e.g., *U.S. ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111 (1st Cir. 2014).

the matter is dismissed, a subsequent action on the same facts will not be barred under this section of the FCA.¹⁶²

Applying **Carter**, courts analyzed if and how matters should proceed when the first-related matter is dismissed. For example, the First Circuit, in **U.S. ex rel. Kelly v. Novartis Pharmaceuticals Corporation**, barred a relator's second complaint as the allegations in her first complaint were still pending.¹⁶³ Kelly was a co-relator to a 2006 complaint.¹⁶⁴ The First Circuit granted her approval to be dismissed without prejudice as a relator to that complaint.¹⁶⁵ In 2012, while the 2006 complaint was pending solely under the co-relator's name, Kelly filed another complaint alleging the same facts.¹⁶⁶ Because the 2006 complaint alleged the same facts and was currently pending, the 2012 complaint was dismissed under the first-to-file rule.¹⁶⁷ This case is distinguished by **U.S. ex rel. Blyn v. Triumph Group, Inc.**, which held the first-to-file bar did not prevent the substitution of relators via an *amended* complaint.¹⁶⁸ Similarly, the district court in **United States v. Pfizer** held that the first-to-file rule did not prevent a relator from amending his or her complaint to include allegations that had failed to meet Rule 9(b) pleading standards in a previous action.¹⁶⁹

Again, relying on **Carter**, the district court in **U.S. v. Unisys Corporation** distinguished the First Circuit's ruling in **U.S. ex rel. Gadbois v. PharMerica Corp.**,¹⁷⁰ holding that the filing of an amended complaint after the first-filed action was dismissed with prejudice did not preclude the application of the first-to-file bar.¹⁷¹ The district court reasoned that the relator's original complaint alleged the same relevant facts and was filed while the first action was still pending, thus precluding the amended complaint.¹⁷²

A district court held in **U.S. ex rel. Cunningham v. Millennium Laboratories, Inc.**, that a relator's cross-claim seeking declaratory judgment that he was entitled to a share of settlement money did not escape the first-to-file rule.¹⁷³ The district court

explained that the rule bars "all related action[s]," which included his cross-claim, as it was based on the same underlying facts of the first-filed claim.¹⁷⁴ Additionally, the first-filed claim, even though it was ultimately dismissed, was still pending at the time of the filing of the cross-claim as it was on review by the First Circuit.¹⁷⁵

Government Action Rule

At least two cases considered the government action restriction found in 31 U.S.C. § 3730(e)(3), which bars "an action...based upon allegations or transactions which are the subject of a civil suit...in which the Government is already a party." The district court in **U.S. ex rel. Bennett v. Biotronik, Inc.**, granted defendant's motion to dismiss, as relator's claims were barred under that FCA provision.¹⁷⁶ The relator had argued that because the first lawsuit had concluded, his action could proceed. The district court, however, contrasted the first-to-file bar with the government action bar, explaining the language in the latter does not include the word "pending," and, thus, precluded the action. Further, the relator's action would provide the government with little or no benefit, as the government was already privy to the alleged scheme via its involvement with the previous lawsuit.

In **Taul ex rel. U.S. v. Nagel Enterprises, Inc.**, the district court determined if the government action bar under § 3730(e)(3) applied by asking "1) whether the allegations and transactions in this case [were] already being or ha[d] been litigated; 2) whether that litigation [was presently] or [had been] in a civil suit or administrative civil money penalty proceeding; and 3) whether the government was a party in the earlier case."¹⁷⁷ The crux lay in whether §981 forfeiture proceeding was a "civil suit or administrative money penalty" within the meaning of the statute. The district court took a narrow reading of the statute, as was supported by the expansion of the availability of *qui tam* actions under the 1986 amendments to the FCA, and held that § 3730(e)(3) did not bar the action.

162. *Carter*, 135 S. Ct. 1970 (2015).

163. 827 F.3d 5 (1st Cir. 2016).

164. *Id.* at *8.

165. *Id.*

166. *Id.* at *9.

167. *Id.*

168. 2016 WL 1664904, at *4 (D. Utah Apr. 26, 2016).

169. 2016 WL 807363 (E.D. Penn. Mar. 1, 2016).

170. 809 F.3d 1, 4-5 (1st Cir. 2015) (allowing a relator to cure jurisdictional defect under § 3730(b)(5) by filing a Rule 15(d) supplemental pleading stating the first-filed action was no longer pending).

171. 178 F. Supp.3d 358 (E.D. Vir. 2016).

172. *Id.* at 374.

173. 2016 WL 4717783 (D. Mass. Aug. 19, 2016).

174. *Id.* at *3.

175. *Id.*

176. 2016 WL 1587215, at *6 (E.D. Cal. April 20, 2016).

177. 2016 WL 304581, at *4 (N.D. Ala Jan. 25, 2016).

FCA Seal Requirements

Prior to December 2016, federal circuits were split on the proper remedy when a relator has violated the FCA's requirement that a complaint must be filed under seal. The Sixth Circuit employed a harsh reading of the FCA's seal requirement, requiring mandatory dismissal of the relator's complaint when the seal was breached. The Ninth Circuit followed a more flexible approach of applying a three-factor test to determine if dismissal of the complaint was necessary, while the Second and Fourth Circuits followed a third route by using a four-factor test.

The Supreme Court resolved the circuit split regarding the consequences of a seal breach in ***State Farm Fire & Casualty Co. v. U.S. ex rel. Rigsby***.¹⁷⁸ There, an attorney for the relators had emailed a sealed document, exposing the existence of a *qui tam* action, to news organizations, which then ran stories on the fraud relators alleged against State Farm in their complaint. The district court rejected State Farm's argument that this required mandatory dismissal and, instead, the district court followed the Fifth Circuit's three-factor test to determine whether dismissal was necessary. Ultimately, it refused to dismiss the case and allowed it to move forward. When the Fifth Circuit affirmed this decision, it deepened the circuit split even more.

In considering the implications of the seal breach, the Supreme Court held that a breach does not require mandatory dismissal. Because the FCA explicitly requires mandatory dismissal of other provisions if violated, the Supreme Court was unwilling to imply the same requirement for a violation of the seal provision when the seal provision does not explicitly include such a requirement.¹⁷⁹ Furthermore, the seal requirement was initially created as a benefit to the government—to keep a relator from notifying the defendant of an ongoing investigation. Therefore, a rigid rule that ignores the government's interest would frustrate this purpose. The Supreme Court, however, did not articulate any particular test to be used in determining when dismissal would be the required remedy for a breach. Rather, the Supreme Court explained that “the question whether dismissal is appropriate should be left to the sound discretion of the district court.”¹⁸⁰ Although the Supreme Court remarked that the factors weighed by the district court (actual harm to the government, severity

“It is proper to infer that, had Congress intended to require dismissal for a violation of the seal requirement, it would have said so.”

-*State Farm Fire & Casualty Co. v. U.S. ex rel. Rigsby*

of the violations and evidence of bad faith) “appear to be appropriate,” it declined to explore those factors more, stating that the standards for dismissal “can be discussed in the course of later cases.”¹⁸¹

Retaliation

The FCA provides protections for whistleblowers in connection with their whistleblowing activities.¹⁸² To establish that an employer retaliated against an employee in violation of 31 U.S.C. § 3730(h), an employee must demonstrate that: (1) the employee engaged in protected activity; (2) the employer knew that the employee was engaged in protected activity; and (3) that, as a result, the employee was discriminated against.¹⁸³ Prior to 2009, “protected activity” was defined as employee conduct “in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section.”¹⁸⁴ In interpreting this language, many courts have adopted the so-called “distinct possibility” standard, holding that “an employee engages in protected activity when litigation is a distinct possibility, when the conduct reasonably could lead to a viable FCA action, or when...litigation is a reasonable possibility.”¹⁸⁵ Since the “distinct possibility” standard was adopted, § 3730(h) has been amended on two occasions. The current definition of “protected activity,” enacted in 2010, covers employee conduct “in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.”¹⁸⁶

Definition of “Protected Activity”

Last year, courts continued to consider the type of conduct that constitutes

178. *State Farm Fire & Cas. Co. v. U.S. ex rel. Rigsby*, 2016 WL 7078622, at *4 (Dec. 6, 2016).

179. *Id.* at *6.

180. *Id.* at *8.

181. *Id.*

182. See 31 U.S.C. § 3730(h).

183. See, e.g., *Carlson v. DynCorp Int'l LLC*, 2016 WL 4435515, at *2 (4th Cir. Aug. 22, 2016).

184. See False Claims Amendments Act of 1986, Pub. L. 99-562, § 4, 100 Stat. 3153, 3157-58.

185. *Eberhardt v. Integrated Design & Const., Inc.*, 167 F.3d 861, 866 (4th Cir. 1999) (internal quotation and citation omitted).

186. 31 U.S.C. § 3730(h)(1) (emphasis supplied).

“protected activity” under the post-2010 FCA’s anti-retaliation provisions at various procedural junctures.

For example, in **Carlson v. DynCorp International LLC**, the Fourth Circuit affirmed the dismissal of an FCA complaint for failure to state a claim under the FCA’s anti-retaliation provision.¹⁸⁷ In so doing, the Fourth Circuit “assume[d], without deciding” that the relator’s proposed standard for applying § 3730(h)’s second prong was correct, i.e., “efforts to stop 1 or more violations” constitute protected activity where those efforts are “motivated by an objectively reasonable belief that the employee’s employer is violating, or soon will violate, the FCA.”¹⁸⁸

In other words, to determine whether a plaintiff has adequately pleaded “protected activity” under the second prong of § 3730(h), the Fourth Circuit asks whether the relator has “allege[d] facts sufficient to show that he believed [his employer] was violating the FCA, that his belief was reasonable, that he took action based on that belief and that his actions were designed to ‘stop 1 or more violations of’ the FCA[.]”¹⁸⁹ With respect to the sufficiency of the relator’s allegations, the Fourth Circuit held that the district court properly dismissed the second amended complaint on the ground that the relator “failed to show that his belief that [the defendant employer] was violating the FCA was objectively reasonable.”¹⁹⁰ Accordingly, the Fourth Circuit deemed the allegations contained in the second amended complaint “entirely speculative[.]” largely due to the relator’s failure “to plausibly allege facts sufficient to show he reasonably believed that” the defendant employer committed a fraud against the government.¹⁹¹

Similarly, in **Fakorede v. Mid-South Heart Center, P.C.**, the district court granted the defendant cardiology clinic’s motion to dismiss on the ground that the relator’s “request for an audit, urgings to comply with the law and challenges relative to attribution of certain expenses to him prior to his termination” were “insufficient, based on caselaw reviewed by the Court, to allege protected activity under [31 U.S.C.] § 3730(h).”¹⁹²

In **Miller v. Abbott Laboratories**, the Sixth Circuit affirmed the district court’s grant of summary judgment in favor of Abbott Laboratories (Abbott), in an action alleging that Abbott terminated a sales representative in retaliation for reporting a potential FCA violation.¹⁹³ The Sixth Circuit agreed with the district court that the Plaintiff “did not present a genuine dispute of material fact whether she engaged in a protected activity” with respect to her FCA retaliation claim, because the Plaintiff failed to demonstrate “an objectively reasonable belief that she was acting to stop a violation of the FCA[.]”¹⁹⁴ Notably, the Plaintiff’s allegations regarding the alleged FCA violation failed as a matter of law, because the Plaintiff acknowledged that a customer of Abbott “would not be induced by [an] offer of \$50 to implement a protocol recommending Abbott’s products[.]”¹⁹⁵

The Seventh Circuit likewise affirmed a district court’s grant of summary judgment in favor of the defendant employer and related entities in **U.S. ex rel. Uhlig v. Fluor Corporation**.¹⁹⁶ With respect to the relator’s allegations, the Seventh Circuit found no false statements were made under the FCA, because the relator failed to demonstrate that the defendant employer breached its contract with the government.¹⁹⁷

In **U.S. ex rel. Johnson v. Kaner Medical Group**, the Fifth Circuit affirmed the district court’s grant of summary judgment in favor of the defendant employer, Kaner Medical Group (KMG).¹⁹⁸ Notably, the Fifth Circuit found that “none of . . . [the] arguments raise[d] a genuine dispute of material fact that KMG acted with the requisite mental state required under the” FCA.¹⁹⁹ Based upon a review of the record, the Fifth Circuit characterized the defendant’s billing practices “negligent,” and therefore, insufficient to meet “the requisite scienter—actual knowledge, deliberate ignorance, or reckless disregard—in submitting reimbursement claims to Medicare and TRICARE[.]”²⁰⁰

In contrast, in **U.S. ex rel. Miller v. Weston Educational, Inc.**, the Eighth Circuit found that sufficient factual issues precluded a grant of summary judgment in favor of the defendant employer.²⁰¹ The plaintiffs had alleged that Heritage College fraudulently

187. No. 14-1281, 2016 WL 4434415 (4th Cir. Aug. 22, 2016).

188. *Id.* at *4 (emphasis supplied).

189. *Id.* at *5.

190. *Id.*

191. *Id.* at *5-*6.

192. 182 F. Supp. 3d 841, 854 (W.D. Tenn. 2016).

193. 648 Fed.Appx. 555, 555-58 (6th Cir. 2016).

194. *Id.* at 555.

195. *Id.* at 562.

196. 839 F.3d 628 (7th Cir. 2016).

197. *Id.* at 634-35.

198. 641 Fed.Appx. 391 (5th Cir. 2016).

199. *Id.* at 394-95.

200. *Id.* In *U.S. ex rel. Bias v. Tangipahoa Parish School Board*, 816 F.3d 315 (5th Cir. 2016), however, the 5th Circuit reversed the district court’s dismissal of the relator’s FCA retaliation claim on the ground that the relator pleaded sufficient facts to survive the defendants’ motion to dismiss. *Id.* at 322-28.

201. 840 F.3d 494 (8th Cir. 2016).

induced the Department of Education “to provide funds by falsely promising to keep accurate student records.”²⁰² The Eighth Circuit found that the district court erred in granting summary judgment in favor of Heritage with respect to the Plaintiffs’ FCA claim on the ground that the Plaintiffs raised material issues of fact regarding “how Heritage understood its obligations and whether it intended to comply with the” program participation agreement with the DOE.²⁰³

In ***Ickes v. Nexcare Health System, L.L.C.***, the district court partially denied the defendant nursing facility’s motion for summary judgment upon finding that the Plaintiff “made a prima facie showing that but for her continued reporting of an alleged violation, she would not have been fired.”²⁰⁴ Similarly, the district court in ***U.S. ex rel. Lindersmith v. John Muir Health***, found that the Plaintiff’s claims survived the defendant’s motion for summary judgment due to contested issues of fact regarding “whether plaintiff’s difficulties with communication and physician/employee relations issues also related to or stemmed from her unpopular efforts to force [the defendant employer] to investigate and address the alleged fraudulent Medicare billing practices.”²⁰⁵

Damages for Retaliatory Acts

A district court decision in ***U.S. ex rel. Mooney v. Americare, Inc.***, provided clarity as to the proper method of calculating damages for retaliatory acts under the FCA.²⁰⁶ Tasked with interpreting the back-pay doubling provision pursuant to § 3730(h), the district court noted an “inherent tension” in the statutory language, which provides that the victim of unlawful retaliation is to be made “whole” while also receiving an award of double back pay.²⁰⁷ The district court found that “doubling damages prior to subtracting mitigation” applied to § 3730(h) because “an employee retaliated against is best made whole by recovering two times the amount of back pay” under that statute.²⁰⁸ The district court explained that an award of double damages prevented some defendants from: (1) “benefitting from the fortuitous event of their victim finding other employment”; and (2) “avoiding the double-damages provision by tendering the undoubled amount in mitigation prior to judgment.”²⁰⁹ Based upon

that construction of § 3730(h), the district court held that the relator’s back pay damages would be “doubled prior to subtracting any mitigation.”²¹⁰

DISCOVERY DEVELOPMENTS IN FCA CASES

In a number of cases from last year, courts considered the scope of investigative authority afforded to the government under the FCA and the related protections applicable to the unique investigative phase of FCA cases. Courts also addressed traditional discovery topics such as the permissible scope of discovery and the waiver of attorney-client privilege through the assertion of a good faith defense in FCA cases.

Scope of CID Authority

Courts increasingly have been called upon to consider the scope of the government’s authority to investigate FCA allegations pursuant to the issuance of a Civil Investigative Demand (CID). Individuals or entities required to respond to CID requests for documents or other information often times are subject to lengthy investigations and typically are without an opportunity to respond to a potential *qui tam* complaint or to engage in discovery themselves.

In ***In re Civil Investigative Demand 15-439***, the subject of an FCA investigation petitioned to set aside a CID, which had been issued after the government had undertaken six years of investigation, reported its findings regarding potential FCA violations and made a settlement demand. The recipient of the CID argued that the government failed to comply with the statutory requirement that the government may only issue the CID before commencing an FCA action or making an election to intervene in a *qui tam* action. Though the district court acknowledged the “compelling argument” that the government’s protracted investigation should have afforded “ample information to determine whether to intervene in a *qui tam* action,” it nevertheless applied a formalistic approach to conclude that the DOJ had not taken any action that would preclude issuance of the CID.²¹¹ The district court explained that “the government has not filed an FCA claim, no

202. *Id.* at 498.

203. *Id.* at 503.

204. 178 F.Supp.3d 578, 596 (E.D. Mich. 2016).

205. 2016 WL 3540954, at *12-13 (N.D. Cal. June 29, 2016).

206. 2016 WL 1237385 (E.D.N.Y. Mar. 28, 2016).

207. *Id.* at *1. The statute states as follows: “Any employee who [has a valid FCA retaliation claim], shall be entitled to all relief necessary to make the employee whole. Such relief shall include reinstatement with the same seniority status such employee would have had but for the discrimination, 2 times the amount of back pay, interest on back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys’ fees.” 31 U.S.C. § 3730(h).

208. *Id.* (internal quotation omitted).

209. *Id.* at *2.

210. *Id.*

211. 2016 WL 427585, at *4, 6 (Aug. 12, 2016).

qui tam action has been unsealed or served, and the government has taken no action that would foreclose its right to intervene in a *qui tam* action.”²¹² The district court’s opinion seemingly leaves little recourse to protest a CID absent movement on a docket, regardless of the extent of DOJ’s prior investigative efforts and its findings of potential violations.

Discoverability of Pre-Intervention and Pre-Indictment Materials

A pair of decisions afforded defendants in civil FCA actions some success in obtaining discovery of materials prepared by the government prior to its decision to intervene in a civil action or bring charges in a criminal action. Discovery of relators’ disclosure statements, however, continued to elude defendants.

In ***U.S. ex rel. Cairns v. D.S. Medical, L.L.C.***, a defendant physician prevailed on a number of discovery issues, set forth in three separate district court opinions issued last year. The district court compelled the government’s production of a PowerPoint presentation that the government made to a hospital where the defendant physician worked. Shortly after the presentation, which was designated as settlement negotiation communications protected from discovery under Federal Rule of Evidence 408, the hospital entered a civil settlement and no criminal charges were filed. The defendant physician successfully argued that the presentation was discoverable under Federal Rule of Evidence 408 as evidence of bias or prejudice because the hospital and some of its employees were under threat of criminal investigation at the time it was made. The defendant physician was unsuccessful, however, in compelling the production of two other government presentations that were made to counsel for other defendants because he did not make a sufficient showing as to potential witness bias or prejudice under FRE 408.²¹³

The district court also compelled production of reports of interviews conducted by the government in response to the argument that the qualified investigative privilege did not apply to those reports.²¹⁴ And, in a third opinion issued in late 2016, the district court granted, in part, the defendant physician’s motion to compel additional interview reports that were “conducted by the [g]overnment before it intervened in [the] action or filed criminal charges”²¹⁵ The district court ordered the government

“There is little guidance as to what constitutes commencing a civil proceeding under section 3730(a) or other false claims law, or making an election under section 3730(b).”

-In re Civil Investigative Demand 15-439

to produce the reports because the reports were considered fact, and not opinion, work product.²¹⁶ Moreover, the district court held that the defendant physician had established a substantial need for the reports because of the significant lapse in time since the interviews were taken.²¹⁷

Another defendant obtained limited discovery related to a DOJ investigation in an effort to assert a statute of limitations defense. In ***United States v. Kellogg Brown & Root Services***, the government countered the defendant’s statute of limitations defense by arguing that a tolling provision applied, such that the government was required to “waive its attorney-client and work product privileges to the extent they would protect information relevant to the factual question of when the United States knew or reasonably should have known of the falsity of KBR’s claims.” Consequently, the district court held that the defendant was entitled to “discovery related to government communications to DOJ Civil that could tend to show DOJ Civil’s knowledge of facts that should have put it on notice of any FCA claims arising out of KBR’s alleged false claims.”²¹⁸

While defendants had some success in obtaining materials prepared by the government prior to intervention or charging decisions, as in previous years, defendants continued to struggle to make inroads in discovering relators’ statutorily required disclosure statements to the government.²¹⁹ In ***U.S. ex rel. Ortiz v. Mt. Sinai Hospital***, for example, the defendants argued that the factual portions of the relators’ disclosure statements should be produced because: (1) they represented ordinary (or “factual”) attorney work product and not opinion work product, and (2) defendants had a substantial need for these documents and could not obtain substantially

212. *Id.* at *6.

213. 2016 WL 3198622, at *1-3 (E.D. Mo. June 9, 2016).

214. 2016 WL 4493679, at *2-4 (E.D. Mo. Aug. 26, 2016).

215. 2016 WL 7437919, at *1 (E.D. Mo. Dec. 22, 2016).

216. *Id.* at *5-6.

217. *Id.*

218. 2016 WL 5344419, at *1, 7 (C.D. Ill. Sept. 16, 2016).

219. See *U.S. ex rel. Spletzer v. Allied Wire & Cable, Inc.*, 2015 WL 7014620, at *3 (E.D. Penn. Nov. 12, 2015); *U.S. ex rel. Fisher v. Oscwen Loan Servicing, LLC*, 2015 WL 4609742, at *4 (E.D. Tex. July 31, 2015); *U.S. ex rel. Fisher v. Homeward Residential, Inc.*, 2015 WL 4610284, at *4 (E.D. Tex. July 31, 2015).

equivalent information without undue hardship. The district court rejected the defendants' arguments, finding that defendants had failed to demonstrate undue hardship as to the factual information at issue. The district court specifically noted that the defendants could have obtained equivalent information through various other discovery means, including deposing the relators. Under this line of reasoning, it likely will remain difficult for defendants to compel the production of a relator's disclosure statement, as defendants will presumably not be foreclosed from taking a relator's deposition or pursuing other discovery means that might elicit information similar to that contained in those disclosure statements.²²⁰

Limiting the Scope of Discovery

Courts are often called upon to determine the scope of discovery in FCA cases in which relators allege wide-ranging fraud schemes. In *U.S. ex rel. Jacobs v. CDS, P.A.*, the district court denied a relator's motion to compel to the extent that it sought the production of documents and information outside of the specific time periods alleged in the complaint. Specifically, the complaint claimed that the defendant medical facilities submitted patient claims to Medicare and Medicaid that falsely certified compliance with the Stark Act and the AKS from January of 2010 through January 2014. The relator, however, sought to compel documents and information for time periods prior to January 2010, despite repeatedly making allegations that clearly fell within the January of 2010 to January 2014 time frame. Based upon the complaint's specific temporal focus, the district court concluded that the relator could not "avoid the limitations established by the complaint."²²¹

Despite the limitations the district court placed on the relator in *Jacobs*, the district court took a more permissive approach to the substantive scope of discovery. Because the complaint was limited to the relator's own physician recruitment agreement with the medical facility, defendants argued that the relator should be precluded from conducting discovery on other doctors' physician recruiting agreements. Even though it acknowledged that discovery is not meant to be "broad and burdensome" on defendants, the district court rejected the defendants'

attempts at limiting the substantive scope of discovery. The district court based this conclusion on the fact that the complaint alleged that "all payments" made during the relevant period violated the FCA and that "other physicians were recruited under similar arrangements" as relator. According to the district court, such allegations were sufficient to broaden the scope of discovery to which the relator was entitled.²²²

Implied Waiver of Attorney-Client Privilege

A district court in the Ninth Circuit highlighted the care defendants must take in asserting defenses within the context of FCA allegations, particularly as to the maintenance of attorney-client privilege. In *U.S. ex rel. Calilung v. Ormat Industries, Ltd.*,²²³ the defendant was accused of "fraudulent actions in connection with federal grant money received pursuant to § 1603 of the American Recovery and Reinvestment Act of 2009 ("ARRA")."²²⁴ The relators argued that the defendant had "affirmatively placed attorney-client communications at issue by asserting a good faith belief that its conduct was lawful" and that those communications should be disclosed.²²⁵

Specifically, the defendant "maintain[ed] that it 'acted reasonably and in good faith in light of all the circumstances and in compliance with all applicable legal requirements,' that its statements regarding legal matters cannot constitute 'false statements of fact,' and that it did not make 'false or knowingly false' statements of fact"²²⁶

In response, the district court stated that the aforementioned defenses went "beyond [the] mere denial of scienter."²²⁷ According to the district court, "[b]ecause such good faith defenses are asserted 'with respect to [Ormat's] understanding and compliance with the law, '[Ormat's] knowledge about the law is vital, and the advice of counsel is highly relevant to the legal significance of [its] conduct.'"²²⁸ As a result, the district court held that the defendant voluntarily had waived attorney-client privilege as to any communications relevant to both this defense and the relators' claims, and must disclose these communications if it wished to continue with its good faith defense.²²⁹

220. 2016 WL 2587393, *8-10 (S.D.N.Y. May 4, 2016).

221. 2016 WL 4146077, at *2-*3 (D. Idaho Aug. 3, 2016).

222. *Id.* at *3-4.

223. 2016 WL 4107682, at *1 (D. Nev. Aug. 1, 2016).

224. *Id.*

225. *Id.* at *3.

226. *Id.* at *4.

227. *Id.*

228. *Id.* (citation omitted).

229. *Id.* at *5.

JUDICIAL REVIEW OF SETTLEMENTS

In ***U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.***, the Fourth Circuit agreed to consider whether the government may veto an FCA settlement when it declined to intervene in the *qui tam* action.²³⁰ The relators and Agape had negotiated a \$2.5 million settlement to resolve FCA allegations, which the government rejected because the dollar amount did not adequately account for the severity of the alleged fraud and the significance of the proposed release of liability. While the Fourth Circuit has yet to issue its ruling as of year-end, the most likely outcome of this interlocutory appeal will reflect a decision by the Fourth Circuit that affirms the conclusion by the district court that the government enjoys an unfettered statutory right to object to a settlement reached between a relator and a defendant in a declined *qui tam* action.²³¹

In ***U.S. ex rel. Howze v. Sleep Centers Fort Wayne***, the relator filed a *qui tam* action asserting state and federal FCA claims and a claim for wrongful termination.²³² After dismissing the wrongful termination claims under *res judicata*, the parties drafted a settlement agreement that would allow the relator to receive 100% of the proceeds from the settlement. After the settlement agreement was drafted, but prior to its execution or government consent, the defendant obtained new counsel and repudiated the agreement. The relator moved to enforce the settlement, arguing that the government knew of the settlement agreement, suffered no harm from the agreement and had declined to intervene in the action. The district court rejected those arguments and held that government consent is required to dismiss an FCA action. The district court further held that it could not enforce an agreement where 100% of the proceeds go to the relator because “[i]n bringing an FCA claim, the relator is acting on behalf of the United States.”

In ***U.S. ex rel. Trinh v. Northeast Medical Services***, the district court rejected a defendant’s arguments that an oral settlement reached with relators and the government should not be enforced. The defendant argued that the terms of the oral settlement agreement, which was reached after a settlement conference and placed on the record in open court, were contingent on satisfactory resolution of any administrative remedies with HHS-OIG. For its part, the state and federal governments accepted the settlement agreement subject to the contingency of final supervisory approvals. After confirmation that both of the contingencies had been satisfied, the

Magistrate Judge concluded that the settlement – which was characterized as “the standard federal and state False Claims Act[] settlement agreement” – was binding and enforceable. For its part, the district court declined to alter or otherwise set aside the judgment entered by the Magistrate Judge.

230. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, Nos. 15-2145 and 15-2147 (4th Cir. argued October 26., 2016).

231. See <http://www.insidethefca.com/2016/10/matt-curley-analyzes-oral-arguments-in-fourth-circuit-agape-case>.

232. *U.S. ex rel. Howze v. Sleep Centers Fort Wayne*, 2016 WL 1358457 (N.D. Ind. Apr. 6, 2016).

STARK LAW/ANTI-KICKBACK STATUTE

Last year, AKS settlements highlighted the importance of strict compliance monitoring for entities operating under the terms of CIAs and the need to ensure that all agreements with referral sources are for a legitimate business reason.

Physician employment arrangements also remained an area of heightened focus, although several courts provided insight into the appropriate structuring of these arrangements in dismissing AKS and Stark Law claims. Other AKS cases also showed a continued focus on kickback schemes related to medical devices and other products.

Notable AKS Developments

In *U.S. ex rel. Williams v. Health Management Associates Inc.* and *U.S. v. Atlanta Medical Center, Inc.*, Tenet Healthcare Corporation and two of its Atlanta-area hospitals, Atlanta Medical Center and North Fulton Hospital, agreed to pay more than \$513 million to resolve civil and criminal allegations of AKS and FCA violations.²³³ Between 2000 and 2013, Atlanta Medical and North Fulton allegedly paid prenatal clinics for referring patients, many of whom were undocumented and indigent, to its labor and delivery, postnatal and infant services. Using sham contracts, the hospitals allegedly paid the clinics for unnecessary, duplicative or substandard translation services, which in certain cases were not actually provided. Tenet allegedly concealed the underlying purpose of the contracts from its legal counsel and violated the terms of its previously-entered CIA with HHS-OIG, which related to a 2006 settlement for \$900 million to resolve allegations of fraudulent billing and AKS violations.

Atlanta Medical and North Fulton pleaded guilty to one count of conspiracy to defraud the United States and agreed to pay \$145 million in criminal forfeiture. Tenet agreed to pay \$368 million to resolve civil FCA allegations related to the two hospitals and two other Tenet hospitals, Spalding Regional Medical Center in Georgia and Hilton Head Hospital in South Carolina. In its press release announcing the settlement, DOJ warned that such physician relationships “exploit vulnerable populations and threaten to drive up the cost of healthcare for everyone” while emphasizing the department’s intolerance for abusive arrangements.²³⁴

Tenet sold Atlanta Medical, North Fulton and Spalding Regional. In return for Tenet’s

remedial actions, DOJ agreed to enter a Non-Prosecution Agreement with Tenet under which Tenet will retain an independent compliance monitor for at least three years.

In *U.S. ex rel. Herman v. Coloplast Corp.*, DOJ announced that it reached a \$20.9 million settlement with two medical products companies for allegedly accepting kickbacks.²³⁵ The relator alleged that Hollister Inc., a manufacturer of disposable healthcare products, paid unlawful kickbacks to Byram Healthcare Centers Inc., a supplier of medical products. The settlement with Hollister resolved allegations that, from 2007 through 2014, Hollister paid kickbacks to Byram in return for marketing promotions, conversion campaigns and other referrals of patients to Hollister’s ostomy and continence care products. In addition, each year from 2009 to 2014, Hollister purportedly agreed to pay Byram \$200,000 for “catalog funding” that was actually intended to induce Byram’s recommendation of Hollister products to patients.

The settlement with Byram resolved the same catalog funding claims, as well as allegations that, in 2012 and 2013, Byram received numerous kickbacks from Hollister and three other manufacturers of ostomy and continence care products in return for Byram’s agreement to conduct promotional campaigns and to refer patients to the manufacturers’ product. The settlement required the company to pay \$127,000 to the state of California to resolve allegations that Byram submitted falsely inflated claims to the state’s Medicaid program, Medi-Cal, in violation of California regulations. In connection with the FCA settlement, Byram also entered into a CIA.

Claims against two other defendants in the lawsuit, Coloplast Corp. and Liberator Medical Supply Inc., were resolved in December 2015 for a total of \$3.66 million. The relator alleged that Coloplast, a manufacturer of ostomy and continence care products, paid unlawful kickbacks including discounts and rebates, to CCS Medical Inc., a supplier of ostomy and continence care products for switching patients to

233. *U.S. ex rel. Williams v. Health Management Associates Inc.*, No. 3:09-cv-00130 (M.D. Ga.); *U.S. v. Atlanta Medical Center, Inc.* No. 16-cr-00350 (N.D. Ga.).

234. <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-513-million-defrauding-united-states-and-making-illegal-payments>.

235. See *U.S. ex rel. Herman, et al. v. Coloplast Corp.*, No. 11-cv-12131-RWZ (D. Mass.).

Coloplast's products, or continuing to recommend and sell Coloplast's products. While the DOJ declined to intervene, it filed a notable Statement of Interest regarding the scope of the discount safe harbor to the AKS as part of pleadings related to a motion to dismiss filed by CCS. In its Statement of Interest, the DOJ reasoned that, "Nothing in the AKS or HHS-OIG regulations suggests that a manufacturer and a distributor can hide a personal services contract within a discount, particularly a discount based on volume or market share. Were such an arrangement found to be permissible, the discount safe harbor would swallow many, if not all, of the other safe harbors."

In ***U.S. ex rel. Witkin v. Medtronic, Inc.***, the district court dismissed several of the claims in a *qui tam* against Medtronic, Inc. and its wholly-owned subsidiary related to its insulin pumps and integrated diabetes management systems.²³⁶ Notably, however, the district court allowed the relator to proceed with FCA claims related to alleged kickbacks paid to healthcare providers to induce them to prescribe Medtronic's diabetes insulin pumps. The district court held that the relator had adequately alleged illegal remuneration and intent to induce physician referrals, and pleaded fraud with sufficient specificity. For example, the relator alleged that Medtronic paid or offered remuneration by running "iPro" clinics in physicians' offices, often without physician involvement (Medtronic paying nurses to staff clinics), while promoting ways in which the physician could bill Medicare for patient iPro clinic visits. The relator alleged that these free services influenced providers to recommend Medtronic insulin pumps to their patients, resulting in government reimbursement in violation of the AKS.

Additionally, the relator alleged that Medtronic paid providers above-market rates to train patients on how to use Medtronic's insulin pumps and provided a variety of other collateral benefits such as free sample devices, meals and travel and luxury accommodations for conferences.

Physician Compensation Focus Continues

Physician employment arrangements with hospitals also remained a significant area of regulatory scrutiny. DOJ announced a \$17 million settlement in ***U.S. ex rel. Hammett v. Lexington County Health Services District***.²³⁷ The lawsuit resolved allegations that Lexington County Health Services District, Inc. d/b/a Lexington Medical Center (LMC) in West Columbia, South Carolina, violated the Stark Law and FCA by acquiring physician practices and employing physicians on terms that were

in excess of fair market value and on terms that were not commercially reasonable.

The relator alleged that LMC acquired the relator's former practice, Columbia Medical Group (CMG) and its associated imaging equipment, for the purpose of securing the imaging referrals from the newly employed physicians. To incentivize the CMG physicians, LMC allegedly offered above fair market value, significantly more than they were previously earning to make up for the loss of ancillary income. The relator also pointed to unusually long-term physician employment contracts designed to lock in compensation as consideration for the value of ancillary services and the hospital's tracking of imaging referrals to question physicians about referral patterns.

In ***U.S. ex rel. Schaengold v. Mem'l Health, Inc.***, the district court approved a \$9.9 million settlement to resolve allegations that Memorial Medical University Center paid its physicians above-market rates to secure referrals for services the hospital billed to Medicare.²³⁸ To alleviate financial pressure due to declining patient volumes, Memorial allegedly aimed to expand its employed primary physician base to ensure that its specialists received referrals. Memorial allegedly acquired a practice projecting a financial loss of \$650,000 for each of the five years after acquisition, and ultimately incurred a loss of roughly \$3 million during a 30-month period, while paying the physicians approximately \$1.5 million during the same 30-month period. Memorial's Board of Directors was eventually informed by the relator of the fair market value issues and its implications. The Board allegedly rejected a plan to correct the overcompensation and voted instead to extend the contracts to avoid losing patient admissions and referrals to a competing hospital.

While the noted settlements reveal the potential liability for improper arrangements, several cases have demonstrated the regulatory flexibility and defensibility of employment if employment arrangements are structured appropriately under Stark Law and AKS. In ***U.S. ex rel. Wall v. Vista Hospice Care, Inc.***, the district court entered summary judgment in connection with relator's FCA claims premised on alleged AKS violations.²³⁹ The relator alleged that employees were paid bonus incentives for hitting admission quotas and census goals, which caused Vista employees to falsify patient records by certifying ineligible patients for hospice care. The district court held that the bona fide employment safe harbor protected the bonus payments to its employees, as it applies to payments to employees of entities in the business of providing covered services, regardless of the specific task being compensated by the bonuses.

236. 2016 WL 2993167 (D. Mass. May 23, 2016).

237. See *U.S. ex rel. Hammett v. Lexington County Health Services District*, Case No. 3:14-cv-03653 (D. S.C.). See also <https://www.justice.gov/opa/pr/south-carolina-hospital-pay-17-million-resolve-false-claims-act-and-stark-law-allegations>.

238. See *U.S. ex rel. Schaengold v. Mem'l Health, Inc.*, No. 4:11-cv-00058-JRH-BKE (S.D. Ga.), settlement approved Feb. 8, 2016.

239. 2016 WL 3449833 (N.D. Tex. June 20, 2016).

In **Cooper v. Pottstown Hospital Co., LLC**, the Third Circuit affirmed dismissal of relator's FCA claims premised on alleged AKS violations.²⁴⁰ The relator, an orthopedic surgeon, filed a *qui tam* complaint alleging that Pottstown contracted to pay physicians for on-call services as an inducement for Medicare referrals. Pottstown allegedly terminated the relator's and two other physician's on-call services agreements after they refused to exclusively refer patients to the hospital. Pottstown executives purportedly used the on-call services as leverage to pressure the relator to relinquish his financial interest in a new, competing surgical facility and offered him a salaried director position. After the relator refused, Pottstown terminated his on-call services agreement. Five months later, after signing another substantially similar on-call services agreement, the relator alleged that Pottstown again terminated the agreement because he began working for another local hospital and would not refer patients exclusively to Pottstown.

In affirming the district court's dismissal of the relator's claims, the Third Circuit noted that the relator failed to establish that the contracts were not arms-length contracts for services legitimately needed by the hospital or that he was compensated in excess of fair market value. The relator's conversations with Pottstown executives failed to establish the hospital's original contractual intent because they occurred seven months after the first agreement was executed. Pottstown was within its rights to terminate the first agreement when it learned of the relator's financial interest in a competing facility and to terminate the second agreement because the relator breached an explicit restrictive covenant. Additionally, the second agreement's provision allowing the relator to retain his affiliation with the competing facility undermined the relator's theory that the hospital intended him to refer patients to Pottstown only.

In **U.S. ex rel. Bingham v. HCA, Inc.**, the district court partially dismissed relator's allegations of Stark Law, AKS and FCA violations.²⁴¹ The relator, a real estate appraiser, alleged that HCA purposefully obscured remuneration it paid physicians to induce them to refer patients to HCA hospitals and locate their offices on HCA hospital campuses. The relator alleged that funds were funneled through third-party developers and landlords in two complex real estate schemes in violation of a CIA. Regarding the first scheme, the district court denied the defendant's motion, finding the relator had plausibly pleaded a Stark Law violation. The district court concluded that HCA could have considered patient referrals through the third-party landlord when assigning office space. Further, the relator pleaded a scenario where physician

tenants drew a profit that varied with the size of their leased office space, which could vary based on the volume or value of referrals. The district court also determined that the relator sufficiently stated a claim of alleged AKS violations, finding that provision of cash flows to tenant physicians, including proceeds from the sale of a medical office building, free parking and a lease arrangement below fair market value, indicated HCA could have been providing financial benefits to physicians to induce referrals.

Regarding the second scheme, the district court granted the defendant's motion, holding that the relator failed to include adequate factual allegations necessary to state a claim under the FCA. Unlike the pleading of the first scheme, the relator did not provide information about specific physician tenants, including their cash flow participation agreements and Medicare referral numbers. Instead, the relator attempted to portray a factually dense scheme without data on clear compensation arrangements between physician tenants and HCA.

Tuomey Endures

After roughly 10 years of litigation, **U.S. ex rel. Drakeford v. Tuomey Healthcare Sys.**, ended with a \$72.4 million settlement before the sale of Tuomey Healthcare System to Palmetto Health. This settlement followed a ruling by the Fourth Circuit, which affirmed the district court judgment ordering Tuomey to pay more than \$237.4 million. This case involved FCA allegations that Tuomey employed and compensated 19 part-time physicians in excess of fair market value and in a manner that varied with the volume or value of their referrals, in violation of the Stark Law.²⁴²

Following the settlement, and in accordance with the Yates Memo, DOJ pursued Tuomey Chief Executive Officer, Ralph J. Cox for his alleged individual culpability in the case. During the Tuomey trial, the government accused Mr. Cox of ignoring and suppressing warnings from a hospital attorney that the physician arrangements raised compliance concerns. DOJ reached a \$1 million civil settlement with Mr. Cox, excluding him for four years from participating in any federal healthcare programs and requiring him to release Tuomey from any indemnification claims. While we might finally be nearing its final chapter, **Tuomey** will continue to serve as a cautionary tale that individuals must be vigilant with compliance involving physician compensation arrangements to avoid personal liability.

240. 651 Fed. App'x. 114 (3d Cir. 2016).

241. 2016 WL 344887 (S.D. Fla. Jan. 28, 2016).

242. 792 F.3d 364 (4th Cir. 2015).

PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENTS

It was another active year for pharmaceutical and medical device companies as enforcement agencies and relators continued to scrutinize industry practices.

In fact, drug and device manufacturers accounted for nearly half of the enforcement recoveries from the healthcare industry last year. Manufacturers also saw enforcement agencies focus on product promotion and speaker program practices, as well as attempt to hold individuals accountable for corporate misdeeds. Moreover, insurers held manufacturers accountable for failing to adhere to Current Good Manufacturing Practices (cGMP).

Speaker Programs Closely Scrutinized

Speaker Programs are an industry norm because prescribers often prefer to be educated about a product by their peers rather than a sales representative. These programs have received significant attention from enforcement agencies and relators because companies typically provide their speakers, who are also prescribers of the companies' products, with honoraria for their involvement. If the programs are not carefully implemented and executed, companies may open themselves up to AKS and FCA liability. Last year, there were mixed outcomes for pharmaceutical and medical device companies that had to defend their speaker program practices.

In *U.S. ex rel. Booker v. Pfizer, Inc.*, after six years and five amended complaints, Pfizer was awarded summary judgment in connection with allegations that it paid kickbacks to physicians through a sham speaker series in order to induce additional prescriptions.²⁴³ The relators, two former sales representatives, suggested, in part, that the series was a sham because the company did not use "nationally known opinion leaders," the programs were conducted with one-on-two lunches instead of large groups and the company tracked the return on investment from its series.²⁴⁴ The district court concluded that Pfizer's series was organized under written contracts that met the requirement the AKS Personal Services safe harbor and that

none of the evidence provided by the relators was sufficient to take it out of the safe harbor.²⁴⁵ The district court explained that having speakers present to small groups may not be the "best, most cost efficient" way to run a speaker series, but it does not "suggest that the program necessarily had a 'universal and improper purpose' of inducing the speaker to prescribe Gedeon."²⁴⁶ Likewise, the district court found it "unremarkable" that Pfizer tracked its return on investment from a series because as a for-profit company that is to be expected and only the attendees – not the speakers – were tracked.²⁴⁷ An appeal is pending for this matter in the First Circuit.

"An FCA relator alleging off-label marketing might be able to satisfy Rule 9(b) and surmount the impediment of implied certification in a case in which it would be obvious to anyone that the use promoted is one that is not approved; but this is emphatically not such a case."

-*U.S. ex rel. Booker v. Pfizer, Inc.*

In *U.S. ex rel. Kroening v. Forest Pharmaceuticals, Inc.*, the district court found that allegations that Forest used speaking fees to pay kickbacks to physicians to induce them to prescribe Forest products did not meet the particularity requirements of Rule 9(b).²⁴⁸ The relator, a former sales representative, claimed that, during 2007 and 2012, Forest provided physicians with lavish meals and money for sham presentations, and, in return, those physicians prescribed Forest products.²⁴⁹ The district court first held that PPACA's amendment of the AKS, although not retroactive, restated existing law, such that the alleged AKS violations that occurred prior to 2010

243. 2016 WL 3017381 (D. Mass. May 23, 2016).

244. *Id.* at 17.

245. *Id.* at 18.

246. *Id.*

247. *Id.*

248. 155 F. Supp. 3d 882 (2016).

249. *Id.* at 885.

still could be the basis for FCA liability.²⁵⁰ Nonetheless, the district court held that the complaint was insufficient because it failed to identify “representative examples of fraud,” and that the relator, as a sales representative, should have been able “to identify specific physicians who received kickbacks, who, in turn, wrote a lot of prescriptions for Forest drugs.”²⁵¹ Despite Forest’s momentary victory, the district court permitted the relator to amend his complaint, and Forest agreed to pay \$38 million to settle the case late last year.²⁵²

NARROWING THE GROUNDS FOR OFF-LABEL PROMOTION-BASED FCA LIABILITY

Off-label promotion remained a target of enforcement activity. Once again, however, the Second Circuit whittled away the types of conduct that may be considered off-label promotion and added to the growing body of case law limiting FCA liability based on this theory.²⁵³

In *U.S. ex rel. Polansky v. Pfizer*, the Second Circuit affirmed the dismissal of the relator’s FCA allegations, which asserted that Pfizer improperly marketed Lipitor as appropriate for patients whose risk factors and cholesterol levels fell outside of the National Cholesterol Education Program (NCEP) Guidelines.²⁵⁴ The relator alleged that the Guidelines were mandatory because they were incorporated into Lipitor’s FDA label, Pfizer induced physicians to prescribe to patients outside the Guidelines, and those patients ultimately sought reimbursement from government healthcare programs in violation of the FCA.²⁵⁵

The Second Circuit rejected the relator’s claim and concluded that the Guidelines “expressly disclaimed perspective force” and were meant only to provide advice.²⁵⁶ In accord with the district court, the Second Circuit found that the NCEP clearly did not intend for their advisory Guidelines to be transformed into a “legal restriction” because the FDA placed them on the drug label.²⁵⁷ In effect, Pfizer’s promotion of Lipitor to patients outside the Guidelines was not off-label promotion.

The Second Circuit expressed skepticism about the relator’s overall theory.

The Second Circuit described “that there is an important distinction between marketing a drug for a purpose obviously not contemplated by the label (such as, with respect to Lipitor, ‘to promote hair growth or cure cancer’) and marketing a drug for its FDA-approved purpose to a patient population that is neither specified nor excluded in the label.”²⁵⁸ This suggests that the Second Circuit believes that FCA liability for off-label promotion should be limited to only the most grievous occurrences.

INDIVIDUAL LIABILITY

Although the Yates Memo was not directed toward pharmaceutical and medical device manufacturers specifically, the industry and its advisors are closely watching what impact the Yates Memo will have on the far-reaching efforts of the government in combatting healthcare fraud relative to their industry.

Since the issuance of the Yates Memo, criminal proceedings pursued against several pharmaceutical and medical device executives have ended in acquittal. On June 17,

“At the very outset of any FCA investigation into a corporate scheme, our attorneys are instructed to focus on both the company and the individuals who may be responsible for the bad conduct. It does not matter whether the investigation is precipitated by a *qui tam* complaint or a referral from a law enforcement partner, or whether a relator actually names individuals as defendants in the *qui tam* action. Our inquiry into individual misconduct now proceeds in tandem with the underlying corporate investigation.”

-Acting Associate Attorney General Bill Baer (June 2016)

250. *Id.* at 891; *but see U.S. ex rel. Arnstein v. TEVA Pharm.*, 2016 WL 750720 at * 20 (S.D.N.Y. Feb. 22, 2016) (“Because the world was not on notice until March 23, 2010, that a claim tainted by an implied certification of compliance with the AKS was a ‘false or fraudulent’ claim, Relators can prevail on a theory of implied certification only with respect to claims that were submitted after March 23, 2010.”)

251. *Id.* at 893-94.

252. See <https://www.justice.gov/opa/pr/forest-laboratories-and-forest-pharmaceuticals-pay-38-million-resolve-kickback-allegations>.

253. In 2012 the Second Circuit reversed a pharmaceutical sales representative’s conviction under the Food, Drug, and Cosmetic Act, holding that the conviction violated his First Amendment right of free speech. See *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

254. 822 F.3d 613 (2nd Cir. 2016).

255. *Id.* at 614.

256. *Id.* at 618.

257. *Id.* at 619.

258. *Id.* at 620.

2016, a Boston jury acquitted W. Carl Reichel, the former president of Allergan PLC's Warner Chilcott unit, of conspiracy to violate the AKS.²⁵⁹ The government alleged that Reichel directed the company's sales force to provide physicians with lavish meals and expensive dinners to induce them to purchase Warner Chilcott products. Notably, Reichel was acquitted despite the fact that Warner Chilcott had pleaded guilty to the underlying conduct, perhaps demonstrating just how difficult it may be for the government to prove individual criminal intent.²⁶⁰

Similarly, in July 2016, two Acclarent executives, William Facteau, the former CEO, and Patrick Fabian, the former Vice President of Sales, were found not guilty of 14 counts of felony fraud related to the off-label promotion of Acclarent's medical devices.²⁶¹ They were convicted, however, of 10 misdemeanor counts of introducing a misbranded and adulterated device into interstate commerce in violation of the federal Food, Drug, and Cosmetic Act, which does not require a demonstration of criminal intent.

Such losses, however, have not slowed DOJ's enforcement efforts. In June 2016, DOJ charged a former district manager and former sales representative of InSys Therapeutics Inc. with violating the AKS based on allegations that sham speaker programs were used to provide physicians with kickbacks to induce the providers to write scripts for Insys' fentanyl spray.²⁶² On December 8, 2016, DOJ charged several other former Insys executives and managers for their role in overseeing a conspiracy to bribe physicians to unnecessarily prescribe its fentanyl-spray product.²⁶³

cGMP Violations Continue to Plague Pharmaceutical and Medical Device Companies

In previous years, we have addressed the various ways that enforcement agencies and relators have used violations of cGMP to pursue FCA liability, but a recent case may have opened the door to a new basis of liability for failure to adhere to cGMPs.

On November 9, 2016, the district court denied GlaxoSmithKline's (GSK) motion

to dismiss RICO claims brought by 41 private insurance companies claiming that wide-scale cGMP violations at GSK's now-defunct Cidra, Puerto Rico plant led them to purchase adulterated, worthless drugs.²⁶⁴ From 1997 to 2006, the Cidra plant consistently failed to manufacture drugs in accordance with cGMPs and sold adulterated drugs in the United States market.²⁶⁵ In 2013, the insurers filed a complaint alleging that GSK fraudulently induced them to pay for billions of dollars of adulterated drugs in violation of RICO, as well as several Pennsylvania laws.²⁶⁶

GSK asserted that the claims should be dismissed because the plaintiffs failed to allege a cognizable injury. The district court disagreed.²⁶⁷ Relying on the Third Circuit's decision in *In Re Avandia*, the court concluded that the insurers "adequately connected GSK's non-disclosure of cGMP violations, and the effect of those violations, on the quality and packaging of certain at-issue drugs, to the [insurers'] payment for drugs they allege had no value."²⁶⁸ The insurers' successful defeat of GSK's motion to dismiss signals to manufacturers that cGMP violations can create liability that extends well beyond FDA warning letters and FCA suits.

Usual and Customary Pricing

Historically, the government has been reticent to intervene in "usual and customary" (U&C) pricing suits, but that trend may change after the Seventh Circuit's decision in *U.S. ex rel. Garbe v. Kmart Corp.*²⁶⁹ There, the Seventh Circuit affirmed that participants in a pharmacies "discount program" constitute members of the "general public" for purposes of determining U&C prices. The relator, an experienced pharmacist, alleged that Kmart artificially inflated its U&C prices of generic drugs for purposes of Medicare Part D reimbursement by ignoring "discount program" sales. Despite Kmart's argument to the contrary, the Seventh Circuit found that the discount program participants were members of the "general public" because, in part, there were virtually no barriers to becoming a member of the program and Kmart permitted anyone to join. The Seventh Circuit explained that "allowing Kmart to insulate high "usual and customary" prices by artificially dividing its customer base would undermine a central purpose of the statutory and regulatory structure"

259. See *United States v. Reichel*, No. 1:15-cr-10324-DPW (D. Mass. June 17, 2016).

260. See <https://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>.

261. See <https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-convicted-crimes-related-sale-medical-devices>.

262. See <https://www.justice.gov/usao-sdny/pr/former-pharmaceutical-company-employees-arrested-participating-fentanyl-kickback-scheme>.

263. See <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>.

264. *Blue Cross Blue Shield Assoc. v. GlaxoSmithKline LLC*, 2016 WL 66112804 (E.D. Pa. Nov. 16, 2016).

265. *Id.* at 2.

266. *Id.* at 3.

267. *Id.*

268. *Id.* at 6.

269. 824 F.3d 632, 635 (7th Cir. 2016).

around U&C pricing.²⁷⁰ Therefore, the Seventh Circuit concluded that prices provided to discount program members represented Kmart's U&C prices.

Other courts already have relied upon **Garbe** to expand the scope of what should be considered when determining U&C prices.²⁷¹ As the case law continues to emerge, pharmacies would be wise to evaluate whether any of their pricing programs are structured in a way that may affect their U&C pricing and open them up to FCA liability.

²⁷⁰ *Id.* at 645.

²⁷¹ See *U.S. ex rel. Schutte v. Supervalu*, 2016 WL 6139913 (C.D. Ill. Oct. 21, 2016) (finding that defendant's price-match discount offer was open to general public, and, therefore, under *Garbe*, represented the U&C prices for impacted drugs).

APPENDIX

APPENDIX - 2016 NOTABLE SETTLEMENTS

HOSPITALS AND HOSPITAL SYSTEMS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 15, 2016	Tri-City Medical Center	Tri-City Medical Center agreed to pay \$3,278,464 to resolve FCA allegations that it maintained 97 financial arrangements with physicians and physician groups that did not comply with the Stark Law. Specifically, the hospital identified five arrangements with its former chief of staff that, in the aggregate, appeared not to be commercially reasonable or for fair market value, as well as 92 financial arrangements with community-based physicians and practice groups that did not satisfy a Stark Law exception because, for example, the written agreements were expired, missing signatures or could not be located. ¹	\$3.278 million
February 17, 2016	Various Hospitals	The government reached settlements with 51 hospitals in 15 states for more than \$23 million to resolve FCA allegations related to implantable cardioverter defibrillators (ICDs) being implanted in Medicare patients that recently had suffered a heart attack or had heart bypass surgery or angioplasty prior to certain waiting periods having passed, in violation of Medicare coverage requirements. Last year, the government reached settlements involving 457 hospitals in 43 states involving similar allegations. These settlements represent the final stage of a nationwide investigation into hospital billing for these devices. ²	\$23 million
February 19, 2016	Adventist Health System Sunbelt Healthcare Corporation	Adventist agreed to pay \$2.09 million to resolve FCA allegations that patients were administered portions of single-dose vials of chemotherapy drugs that were left over from administrations to prior patients; some platinum-based drugs were administered inappropriately; certain infusion services were upcoded; and some patients had to be admitted for treatment because of the foregoing conduct. In January 2012, Adventist voluntarily self-disclosed certain of the above-described conduct to the government and repaid \$819,828.82. This amount will be credited toward the \$2.09 million obligation. ³	\$2.09 million
March 15, 2016	Southern Tennessee Medical Center, LLC (STMC)	STMC agreed to pay \$2,481,856.50 to resolve FCA allegations that it self-disclosed to the government following an investigation by the company's compliance program. Specifically, the allegations were that STMC (1) submitted certain claims for medically unnecessary days of inpatient geriatric psychiatric services and (2) received overpayments relating to the billing of inpatient geriatric psychiatric services for which a physician certification or recertification was not obtained. ⁴	\$2.48 million
April 4, 2016	Southwest Regional Rehabilitation Center	A rehab hospital, which closed in December 2014, agreed to pay \$125,000 to resolve FCA allegations that it billed Medicare for medically unnecessary care to patients that were wrongfully admitted with a diagnosis of generalized debility. ⁵	\$125,000
April 14, 2016	Boston Medical Center (BMC)	BMC and two of its physician practice organizations agreed to pay \$1.1 million to resolve FCA allegations that BMC billed Medicare (1) for more units of a cancer drug than BMC actually infused in its patients; (2) for services at its pre-surgical treatment center even though the global fee for the subsequent surgeries covered those same treatments; and (3) for outpatient podiatry services where the clinical documentation did not support the reasonableness and necessity of the services. After learning of the government investigation, BMC informed the government that it already had repaid certain improperly used funds, had undertaken an audit of the Rituxan issue and was about to start an audit of the pre-surgical treatment billing issue. ⁶	\$1.1 million

- <https://www.justice.gov/opa/pr/california-hospital-pay-more-32-million-settle-allegations-it-violated-physician-self-0>.
- <https://www.justice.gov/opa/pr/fifty-one-hospitals-pay-united-states-more-23-million-resolve-false-claims-act-allegations>.
- <https://www.justice.gov/usao-mdfl/pr/adventist-pay-more-2-million-resolve-false-claims-allegations>.
- <https://www.justice.gov/usao-mdtn/pr/southern-tennessee-medical-center-llc-pay-248-million-settle-false-claims-act-and>.
- <https://mibiz.com/item/23500-battle-creek-rehab-hospital-settles-medicare-false-claims-case>.
- <https://www.justice.gov/usao-ma/pr/boston-medical-center-agrees-pay-11-million-resolve-allegations-it-improperly-billed>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 18, 2016	Bon Secours Health System, Inc.; Dr. Eugene Y. Chang, M.D.	Bon Secours Health System and one of its surgical oncologists agreed to pay \$400,000 to settle FCA allegations that the oncologist billed federal healthcare payors for non-covered breast examinations and ultrasounds, as a result of the oncologist falsifying documents with diagnosis codes, such as "lump or mass in breast," where none existed, and arranging for certain patients to receive screening breast examinations and screening breast ultrasounds at approximately six-month intervals following screening mammograms and improperly billing these services as "diagnostic." ⁷	\$400,000
May 31, 2016	Saint Michael's Medical Center Inc.	Saint Michael's Medical Center agreed to pay \$450,000 to resolve FCA allegations that it billed Medicare and Medicaid for percutaneous coronary interventions, catheterizations and stents performed in its cardiac catheterization lab that were not medically necessary. ⁸	\$450,000
June 30, 2016	Marshall Medical Center (MMC)	MMC agreed to pay \$5.5 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Herren v. Marshall Medical Center, et al. (E.D. Cal.), in which the government declined to intervene, that MMC and related parties improperly billed Medicare and Medi-Cal. Specifically, the complaint alleged that (1) the defendants performed chemotherapy infusions without having a physician present as required; (2) an oncologist referred cancer patients from an oncology clinic to MMC for blood transfusions and then improperly billed Medicare for observation codes that require visits by the doctor in conjunction with the transfusions where no doctor visited; and (3) the oncology clinic's nurses used single dose vials on two subsequent patients and billed Medicare and Medicaid for two dosages. ⁹	\$5.5 million
June 30, 2016	University of Missouri-Columbia	The University of Missouri-Columbia agreed to pay \$2.2 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Galuten v. Univ. of Missouri-Columbia (W.D. Mo.) that it billed Medicare, Medicaid and Tricare for radiology services for which certain attending physicians certified that they had reviewed the images associated with interpretative reports prepared by resident physicians when, in fact, they had not reviewed those images. The university simultaneously settled separate self-disclosed allegations of improper billing that it discovered during its investigation of the <i>qui tam</i> action (see below). As part of the settlements, the university entered into a five-year CIA with HHS-OIG. ¹⁰	\$2.2 million
June 30, 2016	University of Missouri-Columbia	The University of Missouri-Columbia agreed to pay \$3,051,188 to resolve self-disclosed allegations that it improperly billed the government for several years (1) for certain blood tests without a proper supporting order; (2) for Neulasta injections without the proper clinical documentation to support drug-induced neutropenia; and (3) by failing to sufficiently document certain physician arrangements in violation of the Stark Law. ¹¹	\$3.05 million
July 27, 2016	University of Pittsburgh Medical Center (UPMC); University of Pittsburgh Physicians; UPMC Community Medicine, Inc.; Tri-State Neurosurgical Associates – UPMC, Inc.	UPMC and related entities agreed to pay \$2,520,429 to resolve FCA allegations that (1) certain neurosurgeons employed by UPMC billed Medicare for assisting with or supervising surgical procedures performed by other surgeons, residents, fellows, or physician assistants, when those neurosurgeons did not participate in the relevant surgeries to the degree required, and (2) a neurosurgeon billed Medicare for multi-level spinal surgeries for levels of spinal decompression not actually performed. ¹²	\$2.52 million

7. <https://www.justice.gov/usao-edva/pr/bon-secours-health-system-and-doctor-settle-false-claims-act-allegations>.

8. <https://www.justice.gov/usao-nj/pr/newark-hospital-pay-450000-allegedly-billing-health-care-programs-unnecessary-procedures>.

9. <https://www.justice.gov/usao-edca/pr/el-dorado-county-health-care-provider-agrees-pay-55m-resolve-false-claims-act>.

10. <https://www.justice.gov/usao-wdmo/pr/university-missouri-columbia-agrees-pay-united-states-22-million-settle-alleged-false>.

11. https://www.columbiaindependant.com/news/higher_education/settlements-require-mu-to-pay-million-to-u-s-for/article_0971e9ba-3f0f-11e6-912a-db6655516bc0.html.

12. <https://www.justice.gov/usao-wdpa/pr/false-claims-act-violation-upmc-resolved-25-million>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 28, 2016	Lexington County Health Services District, Inc. d/b/a Lexington Medical Center (LMC)	LMC agreed to pay \$17 million to resolve FCA allegations that it maintained improper financial arrangements with 28 physicians in violation of the Stark Law. Specifically, the government alleged that LMC entered into asset purchase agreements for the acquisition of physician practices or employment agreements with 28 physicians that took into account the volume or value of physician referrals, were not commercially reasonable or provided compensation in excess of fair market value. As part of the settlement, LMC agreed to enter into a five-year CIA with HHS-OIG. ¹³	\$17 million
August 1, 2016	St. Joseph's Hospital Health Center	St. Joseph's agreed to pay \$3.2 million to resolve FCA allegations that it billed New York's Medicaid program for mobile-crisis outreach services rendered by personnel who failed to satisfy state regulatory staffing requirements. ¹⁴	\$3.2 million
August 8, 2016	Northampton Hospital Company, LLC d/b/a Easton Hospital	Easton Hospital agreed to pay \$325,000 to resolve FCA allegations that the hospital billed inpatient Medicare Part A claims for routine procedures using particular primary diagnosis codes that did not justify admission to an acute care hospital because the codes correspond primarily to long-term, stable conditions. ¹⁵	\$325,000
August 17, 2016	Westfield Hospital; Dr. Yasin Khan; Dr. Elizabeth Khan; affiliated entities	A hospital, two physicians and affiliated entities, including a related pain clinic, agreed to pay \$690,441 to resolve FCA allegations that they billed for services performed by non-physicians as "incident to" the services of supervising physicians when, in fact, supervising physicians were away from the office or otherwise incapable of supervising. As part of the settlement, they agreed that for the next 2.5 years they would not bill for any services performed by non-physician providers under the "incident to" rate, even if the claims could be billed properly in that manner. ¹⁶	\$690,441
August 24, 2016	Continuum Health Partners, Inc.; Beth Israel Medical Center, d/b/a Mount Sinai Beth Israel; St. Luke's-Roosevelt Hospital Center, d/b/a Mount Sinai St. Luke's; Mount Sinai Roosevelt	Continuum and three of its hospitals agreed to pay \$2.95 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Kane v. Continuum Health Partners, Inc., et al. (S.D.N.Y.), in which the government intervened in 2014, that Continuum improperly retained \$844,000 in overpayments, in violation of CMS's 60-day overpayment rule. Under the settlement, the defendants admitted that (1) Continuum mistakenly submitted claims to Medicaid for payment due to a software error; (2) Continuum was alerted to the software error by the New York State Comptroller; (3) the whistleblower and other Continuum staff then analyzed billing data to discover possible affected claims; (4) the whistleblower was subsequently terminated; (5) Continuum never brought the whistleblower's analysis to the attention of the Comptroller; and (6) Continuum did not fully reimburse Medicaid for claims erroneously billed for more than two years. ¹⁷	\$2.95 million
September 13, 2016	University of Connecticut Health System (UConn Health)	UConn Health agreed to pay \$184,984 to resolve FCA allegations that it billed Medicare using codes for higher paying wound closure procedures, rather than using codes for the lower paying wound closure procedures that were actually performed. ¹⁸	\$184,984

13. <https://www.justice.gov/opa/pr/south-carolina-hospital-pay-17-million-resolve-false-claims-act-and-stark-law-allegations>.

14. <https://www.justice.gov/usao-ndny/pr/st-joseph-s-hospital-pay-32-million-billing-medicare-mental-health-services-rendered>.

15. <https://www.justice.gov/usao-edpa/pr/healthcare-settlement-announced-easton-hospital>.

16. <https://www.justice.gov/usao-edpa/pr/doctors-and-medical-facilities-lehigh-valley-pay-690441-resolve-healthcare-fraud>.

17. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-295-million-settlement-hospital-group-improperly>.

18. <https://www.justice.gov/usao-ct/pr/uconn-health-center-pays-184984-federal-government-settle-overbilling-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 27, 2016	Ralph J. Cox, III	Ralph Cox, the former CEO of Tuomey Healthcare System, agreed to pay \$1 million to resolve FCA allegations related to his involvement in the hospital's employment and compensation of 19 part-time physicians in excess of FMV and in a manner that varied with the volume or value of their referrals, in violation of the Stark Law. As part of the settlement, Cox will be excluded for four years from participating in federal healthcare programs, including providing management or administrative services paid for by federal healthcare programs. In October 2015, Tuomey agreed to pay \$74.9 million to resolve related allegations. ¹⁹	\$1 million
September 28, 2016	Vibra Healthcare	Vibra Healthcare, a national hospital chain, agreed to pay \$32.7 million to resolve FCA allegations it billed Medicare for medically unnecessary services. Specifically, the government alleged that Vibra (1) admitted patients to five of its long term care hospitals (LTCH) and to one of its inpatient rehabilitation facilities who did not demonstrate signs or symptoms that would qualify them for admission; and (2) extended the stays of its LTCH patients without regard to medical necessity, qualification and/or quality of care—in some instances, allegedly ignoring the recommendations of its own clinicians. As part of the settlement, Vibra entered into a five-year CIA with HHS-OIG. ²⁰	\$32.7 million
October 3, 2016	Tenet Healthcare Corporation	Tenet and two of its subsidiaries agreed to pay more than \$513 million to resolve criminal charges and civil FCA claims relating to a scheme to defraud the government and pay kickbacks in exchange for patient referrals. The government alleged that four Tenet hospitals paid bribes and kickbacks to the owners and operators of prenatal care clinics serving primarily undocumented Hispanic women in return for the referral of those patients for labor and delivery medical services. The government alleged that expectant mothers were in some cases told at the prenatal care clinics that Medicaid would cover the costs associated with their childbirth and the care of their newborn only if they delivered at one of the Tenet hospitals, and in other cases were simply told that they were required to deliver at one of the Tenet hospitals, leaving them with the false belief that they could not select the hospital of their choice. To resolve the related criminal matter, two Tenet subsidiaries pleaded guilty, and Tenet HealthSystem Medical Inc. and its subsidiaries agreed to a three-year non-prosecution agreement, which requires the retention of an independent compliance monitor, ongoing cooperation with the government, and an enhanced compliance and ethics program and internal controls. ²¹	\$368 million (civil) \$145 million (criminal)
October 4, 2016	Yavapai Regional Medical Center	Yavapai Regional Medical Center agreed to pay \$5.85 million to resolve FCA allegations that it misreported the hours worked by its employees on its annual cost reports, which artificially inflated the wage index for the Prescott, Arizona area and thus inflated the amount of money Yavapai received from the Medicare program. ²²	\$5.85 million
October 28, 2016	Albert Einstein Healthcare Network; Einstein Practice Plan	Albert Einstein Healthcare Network and Einstein Practice Plan agreed to pay \$968,418.60 to resolve self-disclosed FCA allegations, which the Einstein entities voluntarily self-disclosed to the government, that they billed Medicare for services performed by a cardiologist which were not medically necessary or lacked sufficient documentation, resulting in overpayments to Einstein. ²³	\$968,418

19. <https://www.justice.gov/opa/pr/former-chief-executive-south-carolina-hospital-pays-1-million-and-agrees-exclusion-settle>.

20. <https://www.justice.gov/opa/pr/vibra-healthcare-pay-327-million-resolve-claims-medically-unnecessary-services>.

21. <https://www.justice.gov/opa/pr/hospital-chain-will-pay-over-513-million-defrauding-united-states-and-making-illegal-payments>.

22. <https://www.justice.gov/usao-az/pr/yavapai-regional-medical-center-pay-585-million-resolve-false-claims-allegations>.

23. <https://www.justice.gov/usao-edpa/pr/albert-einstein-healthcare-network-and-einstein-practice-plan-agree-settlement>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 7, 2016	South Miami Hospital	The non-profit regional hospital agreed to pay \$12 million to resolve FCA allegations in the <i>qui tam</i> action styled U.S. ex rel. Burks v. Dylewski, et al. (S.D. Fla.) that it billed federal healthcare programs for medically unnecessary electrophysiology studies and other cardiac procedures allegedly performed by John R. Dylewski, M.D. at the hospital. ²⁴ The relators and Dylewski reached a separate settlement for an undisclosed amount, which the government is not a party to because "HHS-OIG intends to maintain all its rights in instituting, directing, or maintaining any administrative action against" Dylewski. ²⁵	\$12 million

HOSPICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 20, 2016	Hospicio La Paz, Inc.	Hospicio La Paz agreed to pay \$2.5 million to resolve FCA allegations stemming from a government investigation which purportedly uncovered approximately \$1.5 million in "questionable billings" submitted to Medicare Part A. As part of the settlement, Hospicio La Paz agreed to enter into a five-year CIA with HHS-OIG. ²⁶	\$2.5 million
July 13, 2016	Evercare Hospice and Palliative Care	Evercare Hospice and Palliative Care, now known as Optum Palliative and Hospice Care, agreed to pay \$18 million to resolve FCA allegations in two <i>qui tam</i> actions styled U.S. ex rel. Fowler v. Evercare Hospice, Inc. (D. Colo.) and U.S. ex rel. Rice v. Evercare Hospice, Inc. (D. Colo.), which were consolidated and litigated after the government's intervention in 2014. Specifically, the settlement resolved allegations that Evercare claimed Medicare reimbursement for hospice care for patients who were not eligible for such care because they were not terminally ill and because Evercare's medical records did not support that they were terminally ill. The government alleged that Evercare's business practices were designed to maximize the number of patients for whom it could bill Medicare without regard to whether the patients were eligible for and needed hospice. ²⁷	\$18 million
December 2, 2016	Vitas Health Corporation Midwest; related entities	Vitas Health Corporation Midwest and related entities agreed to pay \$200,000 to resolve FCA allegations that it contributed more than \$15,000 to a cancer charity established by Dr. Farid Fata, in exchange for Fata referring 23 patients to Vitas for hospice care, in violation of the AKS. ²⁸	\$200,000

24. <https://www.justice.gov/usao-sdfl/pr/south-miami-hospital-agrees-pay-united-states-12-million-settle-false-claims-act>.

25. No. 14-22079 (S.D. Fla.), Dkt. No. 160-1 at 2 n.1.

26. <https://www.justice.gov/usao-pr/pr/government-reaches-25-million-settlement-healthcare-fraud-matter>.

27. <https://www.justice.gov/opa/pr/minnesota-based-hospice-provider-pay-18-million-alleged-false-claims-medicare-patients-who>.

28. <https://www.justice.gov/usao-edmi/pr/united-states-settles-health-care-fraud-action-involving-allegations-hospice-care>.

HOME HEALTH

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
March 2, 2016	Mark T. Conklin	The former owner, operator and sole shareholder of Recovery Home Care Inc. and Recovery Home Care Services Inc. (RHC) agreed to pay \$1.75 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Simony v. Recovery Home Care, et al. (M.D. Fla.) that Conklin led a scheme whereby RHC paid dozens of physicians thousands of dollars per month to serve as sham medical directors who supposedly conducted quality reviews of RHC patient charts and in fact conducted little to no work, in violation of the AKS and Stark Law. RHC was also a defendant in the <i>qui tam</i> action, and in 2015 the government reached a settlement with RHC's purchaser, National Home Care Holdings, for \$1.1 million to resolve similar allegations. ²⁹	\$1.75 million
May 6, 2016	Trustees of the University of Pennsylvania	The Trustees of the University of Pennsylvania, on behalf of its operating divisions, including the University of Pennsylvania Health System (UPHS), agreed to pay \$75,787 to resolve FCA allegations that Penn Care at Home billed Medicare for home health services not rendered or that were unreasonable or unnecessary. As part of the settlement, UPHS agreed to implement new compliance oversight measures for its home health entities and annually submit certified compliance reports pertaining to those entities to the United States Attorney's Office through 2019. ³⁰	\$75,787
July 7, 2016	MD2U Holding Company; J. Michael Benfield; Greg Latta; Karen Latta; related entities	The holding company for a regional provider of home-based care, its related companies and principal owners (the CEO, CIO and COO) agreed to pay \$3.3 million and a percentage of MD2U's net income over the next five years to resolve FCA allegations in a government lawsuit that MD2U billed government healthcare programs (1) for patients who were neither homebound nor home-limited; (2) for medically unnecessary visits; and (3) at the highest payment codes when a lower code would have been more appropriate. The government also alleged that MD2U cloned medical records through an EMR system that allowed for easy cutting, copying and pasting of medical notes from prior visits in order to justify a subsequent patient encounter. Through a stipulation and court order, MD2U and its principal owners admitted to violating the FCA and causing damages of \$21.5 million under the FCA. As part of the settlement, they also entered into a five-year CIA with HHS-OIG. ³¹	\$3.3 million and a percentage of net income over the next five years
September 14, 2016	Home Bound Healthcare, Inc.; Romy Macaset, Jr.	Home Bound and its owner agreed to pay \$6.8 million to resolve FCA allegations that the home healthcare company and its subsidiaries paid illegal kickbacks to medical directors in the form of monthly fees for the purpose of obtaining patient referrals and not for medical services. The owner pleaded guilty to violating the AKS in a related criminal case. As part of the settlement, Home Bound and related entities entered into a five-year CIA with HHS-OIG. ³²	\$6.8 million
September 30, 2016	Speqtrum, Inc.	Home health agency Speqtrum was ordered to pay \$6.15 million in FCA damages following a grant of summary judgment in favor of the government on liability and a bench trial on damages, in a case alleging that Speqtrum violated the FCA by repeatedly and routinely falsifying records to obtain funds from Medicaid. The government's evidence included documents showing that patient files contained forged signatures or falsified timesheets, including a document showing various practice runs at forging a doctor's signature, which subsequently appeared in a patient file. ³³	\$6.15 million

29. <https://www.justice.gov/usao-mdfl/pr/former-owner-florida-home-health-care-companies-agrees-pay-175-million-resolve-kickback>.

30. <https://www.justice.gov/usao-edpa/pr/settlement-reached-over-universitys-home-health-care-billing>.

31. <https://www.justice.gov/opa/pr/louisville-based-md2u-regional-provider-home-based-care-and-its-principal-owners-admit>.

32. <https://www.justice.gov/usao-ndil/pr/owner-illinois-home-health-company-admits-paying-illegal-kickbacks-20-medical-directors>.

33. <https://www.justice.gov/usao-dc/pr/home-health-care-agency-ordered-pay-over-6-million-false-claims-made-dc-medicaid>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 25, 2016	Best Choice Home Health Care Agency Inc.; Reginald King	Best Choice and its owner and operator, Reginald King, agreed to pay \$1.8 million to resolve FCA allegations resulting from a kickback arrangement between King and Christopher Thomas, who transported patients from their homes to healthcare facilities, whereby King paid Thomas for new patients referred to Best Choice based on a formula which accounted for each hour of service that Best Choice billed to Medicaid. Thomas, the recipient of the alleged kickbacks, filed a <i>qui tam</i> action that led to this settlement. ³⁴	\$1.8 million

SKILLED NURSING FACILITIES AND NURSING HOMES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 12, 2016	RehabCare Group Inc.; Rehab Group East Inc.; Kindred Healthcare Inc.	Contract therapy provider RehabCare and its parent, Kindred Healthcare, agreed to pay \$125 million to resolve FCA allegations that they caused SNFs to bill Medicare for rehabilitation therapy services that were not reasonable, necessary and skilled, or that never occurred. The government alleged that RehabCare's policies and practices, including setting unrealistic financial goals and scheduling therapy to achieve the highest reimbursement level regardless of the clinical needs of its patients, resulted in RehabCare providing unreasonable and unnecessary services to Medicare patients and led its SNF customers to submit artificially and improperly inflated bills to Medicare that included those services. As part of the settlement, RehabCare and Kindred entered into a five-year CIA with HHS-OIG. ³⁵	\$125 million
January 12, 2016	Wingate Healthcare Inc.; THI of Pennsylvania at Broomall LLC; THI of Texas at Fort Worth LLC; Essex Group Management; Frederick County, MD	Four SNF operators agreed to pay \$8.225 million to resolve FCA allegations that they submitted inflated therapy reimbursement claims to Medicare based in part on therapy provided by RehabCare that was not reasonable, necessary and skilled, or that never occurred. As part of the settlement, Wingate Healthcare and Essex Group Management entered into a five-year CIA with HHS-OIG. ³⁶	\$8.225 million
May 3, 2016	Agape Health Management, Inc.; Agape Adult Day Healthcare Center	Agape agreed to pay \$385,917 to resolve FCA allegations that it billed for transportation services purportedly provided to Virginia Medicaid recipients that were not present or transported to the Agape facility on the claimed dates of service. ³⁷	\$385,917

34. <https://www.justice.gov/opa/pr/best-choice-home-health-care-agency-inc-and-its-owner-agree-pay-18-million-resolve-false>.

35. <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-therapy-provider-kindredrehabcare-pay-125-million-resolve-false>.

36. <https://www.justice.gov/usao-ma/pr/united-states-recovers-over-133-million-fraudulent-nursing-home-therapy-claims>.

37. <https://www.justice.gov/usao-edva/pr/alexandria-adult-day-healthcare-center-settles-civil-fraud-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 9, 2016	AJIT Healthcare, Inc. d/b/a Westlake Convalescent Hospital; Dr. Jasvant Modi; Dr. Meera Modi	A nursing home and two physicians who worked at the facility agreed to pay \$3,563,140 to resolve FCA allegations that they participated in a scheme to improperly transfer patients recruited from the "Skid Row" district to a hospital for medically unnecessary services, and then transfer the patients from the hospital to the nursing home for medically unnecessary stays. As part of the settlement, Westlake Convalescent Hospital agreed to enter into a five-year CIA with HHS-OIG. ³⁸	\$3.56 million
September 19, 2016	North American Health Care, Inc. (NAHC); John Sorensen; Margaret Gelvezon	A SNF operator, its chairman of the board (Sorensen), and its senior VP of reimbursement analysis (Gelvezon) agreed to pay a total of \$30 million to resolve FCA allegations that they caused the submission of false claims to federal healthcare programs for medically unnecessary rehabilitation therapy services provided to residents at NAHC SNFs. The government alleged that Gelvezon contributed to this conduct by creating the improper billing scheme, and that Sorensen reinforced this scheme at NAHC facilities. Of the \$30 million settlement, Sorensen and Gelvezon agreed to pay \$1 million and \$500,000.00, respectively. As part of this settlement, NAHC entered into a five-year CIA with the HHS-OIG. ³⁹	\$30 million
September 28, 2016	Health Concepts, Ltd.; John Gage	A SNF operator and its chief operating officer agreed to pay \$2.2 million to resolve FCA allegations that they failed to take sufficient steps to prevent Therapy Resources Management (TRM) from engaging in a pattern and practice of fraudulently inflating the reported amounts of therapy provided to Medicare Part A patients in Health Concepts facilities. Specifically, the government alleged that the SNFs submitted inflated therapy bills because therapists (1) were actually conducting initial evaluations when they claimed to be providing therapy, and (2) reported therapy time using estimates that often were rounded up from the actual minutes of therapy provided, despite Medicare rules specifically prohibiting the reporting of estimated or rounded numbers of minutes. As part of this settlement, Health Concepts entered into a five-year CIA with the HHS-OIG. ⁴⁰	\$2.2 million
October 13, 2016	Whittier Health Network, Inc.; Leo Curtin	A SNF operator and its director of long-term care agreed to pay \$2.5 million to resolve FCA allegations that they failed to take sufficient steps to prevent Therapy Resources Management from engaging in a pattern and practice of fraudulently inflating the reported amounts of therapy provided to Medicare Part A patients in Whittier facilities. Specifically, the government alleged that the SNFs submitted inflated therapy bills because therapists (1) were actually conducting initial evaluations when they claimed to be providing therapy, and (2) reported therapy time using estimates that often were rounded up from the actual minutes of therapy provided, despite Medicare rules specifically prohibiting the reporting of estimated or rounded numbers of minutes. As part of the settlement, Whittier entered into a five-year CIA with HHS-OIG. ⁴¹	\$2.5 million

38. <https://www.justice.gov/usao-cdca/pr/la-nursing-home-two-physicians-pay-over-35-million-resolve-allegations-they>.

39. <https://www.justice.gov/opa/pr/north-american-health-care-inc-pay-285-million-settle-claims-medically-unnecessary>.

40. <https://www.justice.gov/usao-ma/pr/rhode-island-nursing-home-operator-and-chief-operating-officer-pay-22-million-resolve>.

41. <https://www.justice.gov/usao-ma/pr/nursing-home-operator-and-director-long-term-care-pay-25-million-settle-false-claims>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 24, 2016	Life Care Centers of America Inc.; Forrest L. Preston	Life Care and its owner agreed to pay \$145 million to resolve FCA allegations in two <i>qui tam</i> actions styled U.S. ex rel. Taylor v. Life Care Centers of America, Inc. (E.D. Tenn.) and U.S. ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn.), which were consolidated and litigated for several years after the government's 2012 intervention. The government alleged that Life Care submitted false claims for rehabilitation therapy as a result of (1) instituting corporate-wide policies and practices designed to place as many beneficiaries in the Ultra High reimbursement level irrespective of the patients' clinical needs, resulting in the provision of unreasonable and unnecessary therapy; (2) seeking to keep patients longer than was necessary to continue billing for rehabilitation therapy, even after the treating therapists felt that therapy should be discontinued; and (3) carefully tracking the therapy minutes and number of days in therapy to ensure that as many patients as possible were at the highest level of reimbursement for the longest possible period. The settlement also resolved allegations in a separate government lawsuit that Life Care's owner, as the sole shareholder, was unjustly enriched by the company's alleged fraudulent scheme. The settlement amount was based on Life Care's ability to pay. As part of the settlement, Life Care entered into a five-year CIA with HHS-OIG. ⁴²	\$145 million
October 24, 2016	Daybreak Partners, LLC	Daybreak Partners, a holding company for several subsidiaries that operate and manage SNFs, agreed to pay \$5.3 million to resolve FCA allegations that they billed Medicare and Medicaid for materially substandard and/or worthless nursing services at four SNFs because Daybreak failed to: follow doctors' orders and appropriate fall, pressure ulcer and infection control protocols; properly administer medications to avoid medication errors; provide appropriate mental health treatment; answer call lights promptly; provide a habitable living environment, adequate equipment and needed capital expenditures; and investigate and report serious incidents to appropriate authorities on several occasions. As part of the settlement, Daybreak entered into a five-year CIA with HHS-OIG. ⁴³	\$5.3 million

42. <https://www.justice.gov/opa/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act-allegations>.

43. <https://www.justice.gov/usao-ndtx/pr/nursing-home-chain-pay-53-million-resolve-false-claims-act-allegations>.

PHARMACEUTICAL AND MEDICAL DEVICE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 12, 2016	J&L Medical Services, LLC	A medical equipment company agreed to pay \$600,000 to resolve FCA allegations that it regularly utilized unlicensed technicians to provide respiratory therapy services to Medicare and Medicaid beneficiaries, including setting up airway pressure machines, fitting the patients with the masks used with those machines and educating the patients about the use of the machines. The government alleged that under Connecticut law these services could only be performed by licensed respiratory therapists. ⁴⁴	\$600,000
March 1, 2016	Olympus Corporation of the Americas	Medical device maker Olympus agreed to pay \$623.2 million to resolve civil FCA allegations and related criminal charges that it paid millions in kickbacks—in the form of consulting payments, foreign travel, lavish meals, grants and free endoscopes—to doctors and hospitals to secure new business and product sales. To resolve the criminal charges, Olympus entered into a three-year deferred prosecution agreement requiring an independent monitor and other compliance and reform measures. Olympus also entered into a five-year CIA with HHS-OIG. ⁴⁵	\$310.8 million (civil) \$312.4 million (criminal)
March 23, 2016	Respironics, Inc.	A sleep apnea mask maker agreed to pay \$34.8 million to resolve FCA allegations that it paid kickbacks in the form of free call center services to DME suppliers to meet their patients' resupply needs at no charge as long as the patients were using masks that Respironics manufactured; if not, the DME companies would have to pay a monthly fee based on the number of patients who used masks from a Respironics competitor. As part of the settlement, Respironics entered into a five-year CIA with HHS-OIG. ⁴⁶	\$34.8 million
April 27, 2016	Wyeth; Pfizer, Inc.	Wyeth and Pfizer, Inc., which acquired Wyeth subsequent to the relevant allegations, agreed to pay \$784.6 million to resolve FCA allegations in two <i>qui tam</i> actions styled U.S. ex rel. Kieff v. Wyeth, et al. (D. Mass.) and U.S. ex rel. LaCorte v. Wyeth, et al. (D. Mass.), in which the United States and 36 states intervened, that Wyeth reported false and fraudulent prices to Medicaid on two of its proton pump inhibitor (PPI) drugs. These cases proceeded through summary judgment and a final pretrial conference before settling in advance of trial. The government alleged that Wyeth sold the drugs through a bundled sales arrangement in which a hospital could earn deep discounts on the drugs if it placed them on formulary and made them "available" within the hospital. Wyeth allegedly hid from Medicaid the bundled discounts it gave to hospitals in reporting its best prices offered to other customers for their brand name drugs, enabling it to avoid paying hundreds of millions of dollars in rebates to Medicaid. ⁴⁷	\$784.6 million

44. <https://www.justice.gov/usao-ct/pr/connecticut-medical-equipment-company-pays-600000-settle-false-claims-act-allegations-0>.

45. <https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals>.

46. <https://www.justice.gov/opa/pr/respironics-pay-348-million-allegedly-causing-false-claims-medicare-medicaid-and-tricare>.

47. <https://www.justice.gov/opa/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug-rebates>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
April 29, 2016	Byram Healthcare Centers, Inc; Hollister, Inc.	Hollister, a manufacturer of disposable healthcare products, and Byram, a supplier of medical products, agreed to pay \$11.44 million and \$9.3 million, respectively, to resolve FCA allegations that they engaged in an alleged kickback scheme that purportedly included: (1) Hollister paying kickbacks to Byram in return for marketing promotions, conversion campaigns and other referrals of patients to Hollister products; (2) Hollister agreeing to pay Byram the costs of its bonus commissions paid to sales personnel for each new patient order for a Hollister product; (3) Hollister agreeing to pay Byram for "catalog funding," to induce Byram's recommendation of Hollister products to patients; and (4) Byram's receipt of kickbacks from Hollister and other manufacturers in return for its agreement to conduct promotional campaigns and to refer patients to the manufacturers' products. The government also alleged that Byram falsely billed the California Medi-Cal program by failing to account for substantial discounts that Byram knew, at the time of billing, reduced the prices it paid for the products. As part of the settlement, Byram entered into a five-year CIA with HHS-OIG. ⁴⁸	\$20 million
May 27, 2016	Paradigm Spine	A medical device manufacturer agreed to pay \$585,000 to resolve FCA allegations that it caused healthcare providers to submit false claims by (1) marketing the company's coflex-F® device for surgical uses that were not approved by the FDA and (2) giving false recommendations on how to code health claims for procedures involving the coflex® device. ⁴⁹	\$585,000
June 6, 2016	Genentech Inc. and OSI Pharmaceuticals LLC	Genentech and OSI Pharmaceuticals agreed to pay \$67 million to resolve FCA allegations that they made misleading statements to healthcare providers about the effectiveness of the cancer drug Tarceva, which the two companies co-promote. ⁵⁰	\$67 million
June 9, 2016	SALIX Pharmaceuticals, Inc.	A specialty pharmaceutical company agreed to pay \$54 million to resolve FCA allegations that it used sham speaker programs to pay kickbacks to doctors to induce them to prescribe its drugs and medical devices, in violation of the AKS. ⁵¹	\$54 million
June 29, 2016	Cardiovascular Systems, Inc. (CSI)	CSI agreed to pay \$8 million to resolve FCA allegations that it engaged in the following activities to induce doctors to begin to use or continue to use its devices: (1) developing and distributing marketing materials to promote physicians utilizing CSI's devices to referring physicians; (2) coordinating meetings between utilizing physicians and referring physicians; and (3) developing and implementing business expansion plans for utilizing physicians. As part of the settlement, CSI entered into a five-year CIA with HHS-OIG. ⁵²	\$8 million

48. <https://www.justice.gov/usao-ma/pr/byram-healthcare-and-hollister-inc-pay-20-million-resolve-kickback-allegations>.

49. <https://www.justice.gov/usao-md/pr/paradigm-spine-agrees-resolve-false-claims-act-allegations>.

50. <https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-67-million-resolve-false-claims-act-allegations-relating-tarceva>.

51. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-54-million-settlement-against-salix-pharmaceuticals>.

52. <https://www.justice.gov/usao-wdnc/pr/medical-device-company-agrees-pay-8-million-resolve-claims-it-paid-illegal-kickbacks>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 13, 2016	Vesta Brue; LifeTechniques, Inc.; Care Team Solutions, LLC	A federal district court entered a civil judgment of \$4,506,267 against two medical device companies and their owner as part of a settlement agreement to resolve FCA allegations that Brue and her companies made false statements about their personnel, facilities and accounting systems in Small Business Innovation Research grants from the National Institutes of Health. Brue and the companies also acknowledged that they falsely stated on grant reports that they had spent the funds for the grants and in compliance with grant regulations, when, in fact, Brue spent the grant money on personal expenses, such as plastic surgery, jewelry, home renovations and massages, as well as certain business expenses not allowed under the grant regulations, such as costs associated with marketing and promoting her businesses. Brue pleaded guilty in a related criminal case and in March 2016 was sentenced to seven months in prison. ⁵³	\$4.5 million (civil judgment)
July 18, 2016	Bristol-Myers Squibb Company (BMS)	BMS agreed to pay \$30 million to resolve allegations in a state <i>qui tam</i> action styled Cal. ex rel. Wilson v. Bristol-Myers Squibb (Cal. Super. Ct.) brought pursuant to the California Insurance Fraud Prevention Act, which permits whistleblowers to bring civil suits against defendants for allegedly defrauding private insurers. The State of California intervened in the matter and alleged that BMS paid illegal remuneration to physicians and their staff for their participation in various conferences, advisory boards and speaking programs, and provided physicians and their staff lavish meals, liquor, gifts, gift cards and tickets to sporting events, to induce the physicians to increase their prescriptions for the company's drugs. ⁵⁴	\$30 million
July 22, 2016	Acclarent, Inc.	Acclarent, a Johnson & Johnson subsidiary, agreed to pay \$18 million to resolve allegations it caused healthcare providers to submit false claims to federal healthcare programs by marketing and distributing its sinus spacer product for use as a drug delivery device without FDA approval of that use and after the FDA rejected the company's request to expand the approved uses for the product. Acclarent's former CEO and former VP of Sales were convicted in July 2016 following a jury trial in a related criminal case. ⁵⁵	\$18 million
July 28, 2016	Atrium Medical Corp.	A medical device manufacturer agreed to pay \$11.5 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Sullivan v. Atrium Medical Corp. (W.D. Tex.), in which the government declined to intervene, that Atrium violated the AKS by offering inducements to physicians to promote the unapproved use of Atrium stents in patients' arteries. The inducements allegedly included speaker fees, consulting arrangements, sponsorship grants for physician conferences, paid teaching assignments, paid preceptorships, paid product training assignments, other paid physician educations and referral dinners. ⁵⁶	\$11.5 million

53. <https://www.justice.gov/usao-edky/pr/us-district-court-orders-45-million-civil-judgment-against-lexington-woman-and-her>.

54. <https://www.insurance.ca.gov/0400-news/0100-press-releases/2016/release082-16.cfm>.

55. <https://www.justice.gov/opa/pr/johnson-johnson-subsiary-acclarent-inc-pays-government-18-million-settle-false-claims-act>.

56. <https://www.nhbr.com/August-5-2016/Atrium-Medical-Corp-agrees-to-115-million-settlement>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
September 7, 2016	U.S. Healthcare Supply LLC; Oxford Diabetic Supply, Inc.; Jon P. Letko; Edward J. Letko	Two DME companies and their owners and presidents agreed to pay more than \$12.2 million to resolve FCA allegations that they used a fictitious entity to make unsolicited telephone calls to Medicare beneficiaries in order to sell them DME, in violation of the Medicare Anti-Solicitation Statute. In connection with the settlement, Oxford Diabetic Supply agreed to be permanently excluded from participating in federal healthcare programs, and U.S. Healthcare Supply entered into a five-year CIA with HHS-OIG. ⁵⁷	\$12.2 million
October 14, 2016	Telehealth Holdings, LLC; Jerome Hahn	A medical device maker and its owner agreed to entry of a \$1.96 million judgment against them to resolve FCA allegations that they made false statements about their personnel, facilities and accounting systems in federal grant applications and falsely stated in grant reports that they had spent the funds for the grants and in compliance with grant regulations. Hahn and Telehealth allegedly spent the grant money on personal expenses and business expenses not allowed under grant regulations. In a related criminal case, Hahn pleaded guilty and was sentenced to four months in prison. ⁵⁸	\$1.96 million
November 7, 2016	Biocompatibles, Inc.	Medical device manufacturer Biocompatibles pleaded guilty to misbranding its embolic device LC Bead, used to treat liver cancer, and agreed to pay more than \$36 million to resolve criminal and civil FCA liability arising from its conduct. The government alleged that Biocompatibles intended for LC Bead, upon entering the U.S. market, to be used as a drug-delivery device in combination with chemotherapy drugs, despite the lack of FDA approval as a drug-device combination product. Biocompatibles subsequently filed an application with the FDA for approval of LC Bead as a drug-eluting bead combination product, which FDA did not accept because clinical studies did not provide adequate evidence of a therapeutic benefit. Nonetheless, the government alleged that Biocompatibles' distributor routinely advised healthcare providers that LC Bead provided "better" or "superior" therapy for certain types of cancer when, in fact, there was insufficient clinical evidence to support these claims. ⁵⁹	\$25 million (civil) \$11 million (criminal)
November 15, 2016	MedNet, Inc.	A remote cardiac monitoring company agreed to pay more than \$1.35 million to resolve FCA allegations that it paid kickbacks to induce physicians to use the company's services, in violation of the AKS. Specifically, the government alleged that MedNet entered into "fee-for-service" or "direct-bill" agreements with certain hospital and physician clinic customers; charged a fee to the customers for certain services that the company performed in connection with event monitoring and telemetry; and allowed the customers to bill Medicare directly for these same services and retain the reimbursements they received from Medicare, which exceeded the fee that MedNet charged them, in order to induce referrals from those customers for its services. ⁶⁰	\$1.35 million

57. <https://www.justice.gov/opa/pr/diabetic-medical-equipment-companies-pay-more-12-million-resolve-false-claims-act-allegations>.

58. <https://www.justice.gov/usao-edky/pr/lexington-man-and-his-medical-device-company-sued-grant-fraud>; see also *United States v. Hahn, et al.*, No. 16-273 (E.D. Ky.), Dkt. No. 13.

59. <https://www.justice.gov/opa/pr/medical-device-maker-biocompatibles-pleads-guilty-misbranding-and-agrees-pay-36-million>.

60. <https://www.justice.gov/usao-nj/pr/new-jersey-cardiac-monitoring-company-agrees-pay-over-135-million-resolve-claims-it-paid>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 15, 2016	Forest Laboratories LLC; Forest Pharmaceuticals Inc.	Forest Laboratories and its subsidiary agreed to pay \$38 million to resolve FCA allegations that they violated the AKS by providing payments and meals to certain physicians in connection with speaker programs about Bystolic®, Savella®, or Namenda® even when the programs were cancelled (and Forest provided no evidence of a bona fide reason for the cancellation), when no licensed healthcare professionals attended the programs, when the same attendees had attended multiple programs over a short period of time or when the meals associated with the programs exceeded Forest’s internal cost limitations. ⁶¹	\$38 million

PHARMACY SERVICES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 5, 2016	Nashville Pharmacy Services; Kevin Hartman	A pharmacy company specializing in dispensing HIV- and AIDS-related medications and its majority owner paid \$500,000 and agreed to make additional contingency payments over the next five years (potentially up to \$7.8 million) to resolve FCA allegations that they overbilled Medicare and TennCare as a result of: (1) automatically refilling medications without a request from the beneficiary, their physician, or a person acting as the beneficiary’s agent, in violation of TennCare’s contractual requirements; (2) routinely and improperly waiving TennCare and Medicare co-payments without an individualized assessment of those beneficiaries’ inability to pay; (3) improperly using pharmaceutical manufacturers’ co-payment cards to pay the co-payments of certain Medicare recipients; (4) billing for certain medications that were dispensed after the dates of death of 15 beneficiaries; and (5) billing for medications that lacked a valid prescription from a licensed provider for 22 beneficiaries. As part of the settlement, Nashville Pharmacy Services entered into a five-year CIA with the HHS-OIG. ⁶²	\$500,000 (fixed); up to \$7.8 million (contingent)
February 11, 2016	WELLHealth; Topical Specialists; Manish Bansal; Mehul Parekh; Marisol Arcila; Syed Asad	Two compounding pharmacies and four physicians agreed to pay a total of approximately \$10 million to resolve FCA allegations involving improper billing of prescriptions to Tricare. The government alleged that Topical Specialists—a pharmacy created by the four physicians that was unable to obtain separate government healthcare program contracts—sent its prescriptions to WELLHealth, which in turn billed the prescriptions to Tricare. The four physicians allegedly referred costly prescriptions to Topical Specialists, which often were not used by patients and which cost 4-5% of the submitted cost to actually compound. In some cases, the four physicians allegedly recruited other doctors to write prescriptions, promising to share revenue with them. ⁶³	\$10 million
September 14, 2016	Healthmark Investment Trust; Andy Miller; Tracy Miller	Partial owners of compound pharmacy QMedRx agreed to pay \$7.75 million to resolve FCA allegations that the pharmacy billed federal healthcare programs for compounded prescriptions that were tainted within the meaning of the AKS. Another owner (Mark Gilmore) settled related allegations in October 2016 (see following page). ⁶⁴	\$7.75 million

61. <https://www.justice.gov/opa/pr/forest-laboratories-and-forest-pharmaceuticals-pay-38-million-resolve-kickback-allegations>.

62. <https://www.justice.gov/usao-mdtn/pr/nashville-pharmacy-services-settles-false-claims-act-lawsuit>.

63. <https://www.justice.gov/usao-mdfl/pr/united-states-announces-approximately-10-million-settlement-four-physicians-and-two>.

64. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-compound-pharmacy-owner-425>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 17, 2016	Omnicare, Inc.	Omnicare agreed to pay \$28.125 million to resolve FCA allegations that it solicited and received kickbacks—disguised as “grants” and “educational funding” or in the form of tickets to sporting events and funding of meetings in Amelia Island—from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug, Depakote, for nursing home patients. The government also alleged that Omnicare entered into agreements with Abbott by which Omnicare was entitled to increasing levels of rebates from Abbott based on the number of nursing home residents serviced and the amount of Depakote prescribed per resident. ⁶⁵	\$28.125 million
October 21, 2016	Mark Gilmore	A partial owner of compound pharmacy QMedRx agreed to pay \$4.25 million to resolve FCA allegations that the pharmacy billed federal healthcare programs for compounded prescriptions that were tainted within the meaning of the AKS. The government is still pursuing other participants within QMedRx. ⁶⁶	\$4.25 million
November 15, 2016	Lemon Bay Drugs North, Inc.; Brooksville Drugs, Inc.	Two pharmacies agreed to pay a total of \$750,000 to resolve FCA allegations that they provided patients with generic versions of certain medications, but charged Medicare and Medicaid for the brand name versions of those medications. ⁶⁷	\$750,000

MANAGED CARE

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 21, 2016	CenterLight Healthcare Inc.	A managed long-term care organization agreed to pay \$46.7 million to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Heisler v. CenterLight Healthcare Inc., et al. (S.D.N.Y.) that it (1) received Medicaid reimbursements for more than 1,200 members who attended or were referred by social adult day care centers and whose needs did not meet the criteria of the managed care plan; and (2) engaged in improper marketing practices to recruit members through the centers and induced the ineligible members to use the day care centers as their primary source of personal care services. CenterLight admitted that some of these centers in its provider network did not provide services that qualified as personal care services under its Medicaid contract, or were not legally permitted to provide such services. The United States and State of New York partially intervened in this matter to reach this settlement. Other allegations remain under investigation. ⁶⁸	\$46.7 million

65. <https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-pay-over-28-million-settle-kickback-allegations>.

66. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-compound-pharmacy-owner-425>.

67. <https://www.justice.gov/usao-mdfl/pr/lemon-bay-drugs-north-and-brooksville-drugs-agree-pay-750000-resolve-false-claims-act>.

68. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-467-million-settlement-civil-fraud-claims-against>.

LABORATORY, PATHOLOGY, RADIOLOGY AND DIAGNOSTICS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 8, 2016	Dr. David G. Bostwick	The former owner of Bostwick Laboratories agreed to pay up to \$3.75 million to resolve FCA allegations in the <i>qui tam</i> action styled U.S. ex rel. Daugherty v. Bostwick Laboratories, et al. (S.D. Ohio) that Bostwick (1) directed Bostwick Laboratories to bill for cancer detection tests that were medically unnecessary and performed without the treating physicians' consent or order, and (2) offered various discounts and billing arrangements to treating physicians to induce them to refer business to Bostwick Laboratories in violation of the AKS. In 2014, Bostwick Laboratories agreed to pay \$6.05 million to resolve the allegations in this matter, in which the government previously declined to intervene. ⁶⁹	\$2.6 million (fixed); \$1.125 million (contingent)
January 29, 2016	Rose Radiology Centers	A radiology services provider agreed to pay \$8.71 million to resolve FCA allegations that it improperly billed for radiology procedures as a result of (1) administering contrast dye during MRI scans on patients without direct physician supervision as required by federal regulations; (2) accepting orders from chiropractors but billing for them as if they were actually ordered by a Rose Radiology employed physician; (3) the procedures not being ordered by the patients' treatment providers; (4) the procedures being performed at facilities not enrolled as authorized Medicare providers, but billed as though they were performed at a different, authorized facility; and (5) a kickback scheme in which Rose Radiology provided referring physicians with financial incentives in the form of lunches, gift cards and tickets to concerts or sporting events in exchange for receiving radiology referrals. As part of the settlement, Rose Radiology entered into a five-year CIA with HHS-OIG. ⁷⁰	\$8.71 million
March 8, 2016	21st Century Oncology, Inc.; South Florida Radiation Oncology, LLC	A radiation oncology provider and a subsidiary agreed to pay \$34,695,243 to resolve FCA allegations that they performed and billed for Gamma function procedures (1) where the procedure served no medically appropriate purpose, (2) when no physician reviewed the Gamma function results until seven or more days after the last day patients received radiation treatment therapy, and (3) when no Gamma function result was available due to technical failures in the imaging equipment. ⁷¹	\$34.69 million
April 11, 2016	PremierTox 2.0, Inc.	A provider of drug urine screening services agreed to pay \$2.5 million to resolve FCA allegations that PremierTox and Nexus Lab, a name under which PremierTox previously did business, (1) engaged in a swapping arrangement, in which Nexus gave below cost discounts on its urine drug screen tests to patients without insurance, in exchange for physicians' referring their patients with Medicare or TennCare coverage to Nexus; (2) billed for laboratory testing that was medically unreasonable and unnecessary; and (3) provided point of care testing cups to medical offices free of charge to induce those providers to use PremierTox's services. ⁷²	\$2.5 million

69. <https://www.justice.gov/opa/pr/former-owner-bostwick-laboratories-agrees-pay-375-million-resolve-allegations-unnecessary>.

70. <https://www.justice.gov/usao-mdfl/pr/rose-radiology-centers-agree-pay-more-8-million-false-billing-medical-procedures-and>.

71. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-21st-century-oncology-nearly>.

72. <https://www.justice.gov/usao-wdky/pr/premiertox-pays-united-states-and-tennessee-25-million-resolve-false-claims-act-lawsuit>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
June 1, 2016	Dr. Jonathan Oppenheimer; OPKO Health, Inc.; OPKO Lab, LLC	The former owner of a drug testing laboratory and the laboratory's successor entities agreed to pay \$9.35 million to resolve FCA allegations that the laboratory and former owner engaged in a kickback scheme whereby they made donations toward EHR systems purchased by their client physician practices, and, in making those contributions, violated the AKS's EHR safe harbor and the Stark Law's EHR exception by (1) directly considering the volume and/or value of referrals and business, including return on investment, between the laboratory and the physicians' practice when determining whether to make an EHR donation and the amount of the donation; (2) improperly considering the volume of Medicare business supplied by the physician practice when considering an EHR donation; and (3) occasionally withholding previously agreed-upon EHR donation payments until they received a certain number of referrals from the physicians' practice. The government also alleged that the laboratory billed Medicare and Tricare for "FISH" tests despite an adverse coverage determination for the particular type of test being used. As part of the settlement, Oppenheimer agreed to be excluded from participating in federal healthcare programs for five years. ⁷³	\$9.35 million
July 12, 2016	Biosound Medical Services Inc.; Heart Solution PC; Nita K. Patel; Kirtish N. Patel	Two individuals and their diagnostic imaging companies were ordered to pay more than \$7.75 million following a grant of summary judgment in favor of the government in an FCA case in which the court found the defendants liable for submitting false claims to Medicare for thousands of falsified diagnostic test reports and the underlying tests, and for neurological tests conducted without physician supervision. In August 2016, the two individuals were each sentenced to more than six years in prison in a related criminal case. ⁷⁴	\$7.75 million
July 22, 2016	Preferred Imaging, LLC	An operator of independent diagnostic testing facilities (IDTFs) agreed to pay \$3.51 million to resolve FCA allegations that it improperly billed Medicare, Medicaid and Tricare for procedures performed without a supervising physician on-site, as required for certain procedures (e.g., administration of contrast dye) performed by IDTFs. As part of the settlement, Preferred Imaging entered into a five-year CIA with HHS-OIG. ⁷⁵	\$3.51 million
November 16, 2016	Zwanger-Pesiri, Inc.	A radiology company agreed to pay \$8.153 million and forfeit \$2.4 million to resolve FCA civil allegations and related criminal charges that the company "bundled" the tests it performed, such that when a patient's treating physician ordered one test to be performed, Zwanger-Pesiri would automatically perform a related but unordered test. The civil settlement also resolved allegations that Zwanger-Pesiri billed Medicare and Medicaid programs for procedures performed or supervised by physicians who were not properly credentialed, or which were performed at an unauthorized practice location. As part of the global resolution, Zwanger-Pesiri pleaded guilty to the related criminal charges and agreed to enter into a five-year CIA with HHS-OIG. ⁷⁶	\$8.153 million (civil) \$2.4 million (criminal)
December 13, 2016	Elite Lab Services, LLC; Gerard Dengler; Suzanne Dengler	Elite Lab Services and its owners agreed to pay \$3.75 million as part of a settlement in which they admitted submitting false claims to Medicare with inflated mileage calculations beyond those actually driven by Elite Lab employees. Elite Lab Services agreed to be excluded from participating in Medicare for eight years, Gerard Dengler will be excluded for 10 years and Suzanne Dengler agreed to be for eight years. ⁷⁷	\$3.75 million

73. <https://www.justice.gov/usao-mdtn/pr/former-ceo-physician-and-drug-testing-laboratory-pay-935-million-settle-false-claims>.

74. <https://www.justice.gov/usao-nj/pr/new-jersey-couple-and-two-diagnostic-companies-ordered-pay-775-million-falsifying>.

75. <https://www.justice.gov/usao-ndtx/pr/preferred-imaging-llc-pay-3510000-resolve-false-claims-act-allegations>.

76. <https://www.justice.gov/usao-edny/pr/long-island-radiology-company-zwanger-pesiri-inc-pleads-guilty-federal-health-care>.

77. <https://www.justice.gov/usao-edtx/pr/east-texas-laboratory-company-and-owners-agree-375-million-payment-false-medicare>.

SPECIALTY CARE AND OTHER PROVIDER ENTITIES

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 12, 2016	Rheumatology & Dermatology Associates, P.C.; Dr. George R. Woodbury	A dermatologist and his medical practice agreed to pay \$450,000 to resolve FCA allegations that the practice billed Medicare for unnecessary dermatological surgical procedures and office visits. ⁷⁸	\$450,000
January 27, 2016	National Care EMS; Mohammed Elsaleh; Husam Alsaleh	The former owner and operator (Elsaleh) of ambulance company National Care EMS, which is no longer in business, and the owner and operator (Alsaleh) of a successor company by the same name agreed to pay \$245,000 to resolve FCA allegations that Elsaleh and his company provided free and heavily discounted ambulance transports to various nursing facilities and hospitals in exchange for the institutions' referral of more lucrative Medicare and Medicaid business, in violation of AKS. ⁷⁹	\$245,000
February 12, 2016	Riachi, Inc.; Center for Advanced Pelvic Surgery, LLC; Dr. Labib E. Riachi	A physician and two companies he owns and operates agreed to pay \$5.25 million to resolve FCA allegations that they falsely billed federal healthcare programs for various tests that were never provided and for physical therapy services that were not performed by a qualified therapist. The physician agreed to be excluded from participation in federal healthcare programs for 20 years. ⁸⁰	\$5.25 million
February 17, 2016	Lake Champlain Gynecologic Oncology P.C. (LCGO); Dr. Gamal H. Eltabbakh	Eltabbakh and his gynecologic cancer center agreed to pay \$500,000 to resolve FCA allegations that a portion of the drugs used by Eltabbakh in chemotherapy treatments (1) were purchased by LCGO from a Canadian drug distributor and other sources; and (2) had not received final marketing approval from the FDA and were not covered by Medicare and Medicaid. ⁸¹	\$500,000
April 13, 2016	Florida Pain Medicine Associates, Inc.; Dr. Bart Gatz; Dr. Alexis Renta; Dr. Albert Rodriguez	Florida Pain Medicine Associates and its owners agreed to pay \$1.1 million to resolve FCA allegations that they billed Medicare for medically unnecessary nerve conduction studies (NCS), as the NCSs were often administered without an accompanying electromyography test, thereby substantially decreasing the diagnostic value of the procedure. As part of the settlement, the practice entered into a three-year CIA with HHS-OIG. ⁸²	\$1.1 million
April 18, 2016	Margaret Kopchick, M.D.; Russell Burken, M.D.; Toccoa Clinic Medical Associates	Two dermatologists and their practice agreed to pay \$1.9 million to settle FCA allegations that they (1) billed Medicare for E/M services on the same day as procedures where no significant and separately identifiable service was performed, in violation of Medicare rules; and (2) upcoded E&M services to higher levels than were appropriate, leading to overpayments by Medicare. As part of the settlement, the dermatologists and their practice group entered into a five-year CIA with HHS-OIG. ⁸³	\$1.9 million
May 31, 2016	REM Connecticut Community Services, Inc.	A former operator of group homes that provided residential and day services to the intellectually disabled and at-risk youth agreed to pay \$1.5 million to resolve FCA allegations that it received overpayments from the Connecticut Medicaid Program, as a result of its submission of annual cost reports, which included certain interest expenses as allowable costs that were in fact not allowable under the state's cost standards. ⁸⁴	\$1.5 million

78. <https://www.justice.gov/usao-wdtn/pr/local-dermatologist-cordova-based-medical-practice-pay-450000-overbilling-medicare>.

79. <https://www.justice.gov/usao-sdtx/pr/ambulance-company-owners-agree-pay-more-245000-resolve-kickback-allegations>.

80. <https://www.justice.gov/usao-nj/pr/new-jersey-doctor-two-companies-agree-pay-525-million-allegedly-submitting-bogus-claims>.

81. <https://www.justice.gov/usao-vt/pr/united-states-and-vermont-doctor-resolve-matter-involving-non-fda-approved-drugs-and>.

82. <https://www.justice.gov/usao-sdfl/pr/florida-pain-medicine-associates-and-its-owners-agree-pay-over-one-million-dollars>.

83. <https://www.justice.gov/usao-ndga/pr/dermatology-physicians-and-practice-pay-19-million-settle-false-claims-act>.

84. <https://www.justice.gov/usao-ct/pr/former-connecticut-group-home-operator-pays-15-million-settle-overbilling-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
June 30, 2016	Dr. Asad Qamar; Institute of Cardiovascular Excellence (ICE)	Dr. Asad Qamar, a cardiologist, and his practice, ICE, agreed to pay \$2 million and release any claim to \$5.3 million in suspended Medicare funds to resolve FCA allegations in two <i>qui tam</i> actions styled U.S. ex rel. Doe v. Institute of Cardiovascular Excellence, et al. (M.D. Fla.) and U.S. ex rel. Taylor v. Institute of Cardiovascular Excellence, et al. (M.D. Fla.), which were consolidated and briefly litigated after the government's intervention in 2014. The government alleged that the defendants billed Medicare, Medicaid and Tricare for medically unnecessary procedures and paid kickbacks to patients by waiving Medicare copayments irrespective of financial hardship to induce patients to agree to unnecessary and invasive procedures and other services. Qamar also agreed to a three-year period of exclusion from participating in any federal healthcare program followed by a three-year Integrity Agreement with HHS-OIG. ⁸⁵	\$7.3 million
July 5, 2016	Drayer Physical Therapy Institute, LLC	An operator of outpatient physical therapy clinics agreed to pay \$7 million to resolve FCA allegations that it billed federal healthcare programs for therapy services being provided to multiple patients simultaneously as though the services were being provided by a physical therapist or physical therapist assistant to one patient at a time. As part of the settlement, Drayer also entered into a five-year CIA with HHS-OIG. ⁸⁶	\$7 million
July 27, 2016	Deremedx Dermatology, P.C. d/b/a Dermatique; Dr. Barry A. Solomon	A dermatologist and his solo practice agreed to pay \$302,227 to resolve FCA allegations that he improperly billed Medicare and Medicaid (1) for services performed as if he were supervising the procedures even though he was not in the office—in some cases, not in the country—during the procedures; (2) for so-called “impossible days,” in which he submitted claims for more hours than he could have possibly worked; and (3) by double billing Medicare for certain examinations and procedures. As part of the settlement, Solomon entered into a three-year Integrity Agreement with HHS-OIG. ⁸⁷	\$302,227
July 29, 2016	LXE Counseling, LLC; Lexie Darlene George a/k/a Lexie Darlene Batchelor	A provider of behavioral and mental health counseling and its owner and CEO agreed to a stipulated order requiring them to pay \$4,752,101 to resolve FCA allegations in a <i>qui tam</i> action styled U.S. ex rel. Pittman v. LXE Counseling, et al. (W.D. Okla.), in which the government intervened in 2015, that they submitted or caused to be submitted the false Medicaid claims for (1) services provided by persons not qualified to provide those services; (2) services where the defendants altered dates or times of services or altered service codes to make otherwise ineligible claims eligible for reimbursement; (3) face-to-face services that were double-billed for the same dates and times by the same person; (4) face-to-face services performed by Batchelor while she was instead attending a funeral, a wedding or on trips; (5) telemedicine services when LXE and its providers were not authorized or approved by Oklahoma Medicaid to provide such services; and (6) rehabilitation services provided to patients who never received any psychotherapy services, in violation of Oklahoma Medicaid regulations. LXE and Batchelor agreed to be excluded from participation in Medicaid and Medicare for five years. ⁸⁸	\$4.75 million

85. <https://www.justice.gov/opa/pr/florida-cardiologist-and-his-practice-pay-millions-and-agree-three-years-exclusion-resolve>.

86. <https://www.justice.gov/usao-sc/pr/drayer-physical-therapy-institute-llc-settle-false-claims-act-case-7000000>.

87. <https://www.justice.gov/usao-edny/pr/long-island-dermatologist-settles-claims-he-defrauded-medicare-and-medicaid>.

88. <https://www.justice.gov/usao-wdok/pr/united-states-and-state-oklahoma-obtain-47-million-judgment-against-behavioral-health>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
August 5, 2016	Sweet Dreams Nurse Anesthesia (Sweet Dreams)	A group of anesthesia businesses, collectively known as Sweet Dreams Nurse Anesthesia, agreed to pay \$1,046,494 to resolve FCA allegations that it paid kickbacks to healthcare providers with the intent to induce referrals of Medicare and Medicaid patients, in violation of the AKS. Specifically, the government alleged that (1) Sweet Dreams provided free anesthesia drugs to ambulatory surgery centers (ASCs) in exchange for the ASCs granting Sweet Dreams an exclusive contract to provide anesthesia services at those ASCs; and (2) a Sweet Dreams affiliate funded the construction of an ASC, in exchange for contracts for Sweet Dreams' selection as the exclusive anesthesia provider at that facility and other affiliated podiatry-based ASCs. As part of the settlement, Sweet Dreams entered into a five-year CIA with HHS-OIG. ⁸⁹	\$1.046 million
August 30, 2016	Jesus Villegas, DDS; Fairfield Pediatric Dentistry, LLC; Haven Pediatric Dentistry, LLC	A dentist and his two pediatric dental clinics agreed to pay \$1,367,466 to resolve FCA allegations that they improperly billed Medicaid for pediatric dental x-rays taken by dental assistants who were not certified by the Dental Assisting National Board as required by Connecticut law. As part of the settlement, Villegas entered into a three-year Integrity Agreement with HHS-OIG. ⁹⁰	\$1.367 million
August 30, 2016	Dr. John P. Balko; John Balko & Associates, Inc. d/b/a Senior Healthcare Associates (SHA)	An audiologist and his healthcare company agreed to pay \$930,000 to resolve FCA allegations that they billed for services provided to nursing home residents—including earwax removal procedures, podiatry, and certain E/M services—which were not medically necessary, not authorized or requested by patients, not supported by patient medical records or were provided in reliance upon improper standing orders. In addition, SHA agreed to be excluded from participation in federal healthcare programs for 10 years. ⁹¹	\$930,000
August 31, 2016	Clear Vue Eye Center, Inc.; Dr. Monique Barbour	Clear Vue Eye Center and its owner agreed to pay \$1 million to resolve FCA allegations that they billed Medicare for excessive patient visits at nursing homes and assisted living facilities—often for more than 20 hours in a 24-hour period, with little patient benefit, and with an inflated billing code—and for procedures purportedly performed while Barbour was out of the country. ⁹²	\$1 million
August 31, 2016	Physicians Group Services, P.A. d/b/a Coastal Spine and Pain	A surgery and pain management clinic agreed to pay \$7.4 million to resolve FCA allegations that, despite appropriately performing qualitative drug tests, the clinic also performed and billed for more expensive and more specific quantitative drug tests for all patients, regardless of the result of the qualitative test, which was medically unnecessary. The government developed this case through the proactive review of claims data, as the clinic was a statistical outlier in billing for quantitative drug test screens. As part of the settlement, Coastal Spine and Pain entered into a five-year CIA with HHS-OIG. ⁹³	\$7.4 million
October 3, 2016	Orthopedic Associates of Northern California; San Bernadino Medical Orthopaedic Group, Inc. d/b/a Arrowhead Orthopaedics; Reno Orthopaedic Clinic	Three orthopedic clinics agreed to pay a combined \$2.39 million to resolve FCA allegations that they purchased deeply discounted osteoarthritis medications, known as viscosupplements, that were reimported from foreign countries and billed them to state and federal healthcare programs, even though such reimported viscosupplements were not reimbursable by those programs. ⁹⁴	\$2.39 million

89. <https://www.justice.gov/usao-mdga/pr/sweet-dreams-nurse-anesthesia-group-pays-more-1-million-resolve-kickback-allegations>.

90. <https://www.justice.gov/usao-ct/pr/pediatric-dentist-pays-13-million-settle-false-claims-act-allegations>.

91. <https://www.justice.gov/usao-wdpa/pr/mercer-county-doctor-practice-settle-false-claims-act-allegations>.

92. <https://www.justice.gov/usao-sdfl/pr/clear-vue-eye-center-and-its-owner-agree-pay-one-million-dollars-resolve-false-claims>.

93. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-coastal-spine-and-pain-74>.

94. <https://www.justice.gov/usao-edca/pr/orthopedic-clinics-pay-239-million-settle-allegations-billing-federal-health-care>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
October 21, 2016	Hudson Valley Associates, R.L.L.P.	A hematology and oncology practice agreed to pay \$5.31 million to resolve an FCA matter and admitted to (1) routinely waiving Medicare beneficiaries' copayments without an individualized documented determination of financial hardship or exhaustion of reasonable collection efforts and billing Medicare for the waived copayments; and (2) overbilling Medicare and Medicaid for E/M service codes, in addition to billing for routine procedures on the same date, even though the practice had not documented that it provided any significant, separately identifiable E/M services to the beneficiaries. In addition, Hudson Valley entered into a five-year CIA with HHS-OIG. ⁹⁵	\$5.31 million
November 22, 2016	CleanSlate Centers, Inc. and Total Wellness Centers, LLC d/b/a CleanSlate	Two operators of opioid addiction treatment centers agreed to pay \$750,000 to resolve allegations that they (1) violated the Controlled Substances Act and DEA regulations by routinely contacting pharmacies representing that physicians had prescribed buprenorphine for patients when, in fact, only midlevel practitioners had seen the patients and by having part-time CleanSlate physicians sign the prescriptions, backdating them to the visit dates; and (2) violated the FCA by improperly billing Medicare for patient visits using physicians' identification numbers when, in fact, the patients saw midlevel practitioners and no physicians were on clinic premises to supervise those practitioners. ⁹⁶	\$750,000
December 6, 2016	Eyeland Optical Centers	A chain of eye care centers agreed to pay more than \$135,000 to resolve FCA allegations that it billed Medicaid for more than four lenses per year, in violation of Pennsylvania Medicaid's regulations, and then retained those payments upon becoming aware that it had done so. ⁹⁷	\$135,328
December 7, 2016	Lifepoint Dental Group, LLC; Aaron Blass; Angelina Blass; Mindy Richtsmeier; Brad Richtsmeier	A dental clinic and its owners agreed to pay more than \$300,000 to resolve FCA allegations that they billed for dental procedures, including scalings and root planings, which were either medically unnecessary or not actually performed. ⁹⁸	\$300,000

95. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-531-million-civil-settlement-against-hematology>.

96. <https://www.justice.gov/usao-ma/pr/cleanslate-addiction-treatment-centers-settle-allegations-unlicensed-prescribing-and>.

97. <https://www.justice.gov/usao-edpa/pr/united-states-settles-eyeland-optical-centers-over-medicare-false-claims>.

98. <https://www.justice.gov/usao-ndia/pr/iowa-dental-clinic-and-its-owners-agree-pay-more-300000-resolve-allegations-clinic>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
December 7, 2016	Southeast Orthopedic Specialists	An orthopedic medical group agreed to pay \$4.488 million to resolve FCA allegations that it engaged in several types of questionable billing practices, including that it (1) certified that it met certain EHR “meaningful use” standards when the practice had not actually done so; (2) billed for certain claims as “incident to” physician supervision when no physician was present or there was no verification of any physician being present; (3) billed for certain claims using Modifier 25 signifying that a separate E/M service was performed even when there was no such separate service; (4) billed for certain claims using Modifier 59 signifying that two procedures, rather than one, were billable even when these procedures should have more appropriately been billed as one such procedure; (5) scheduled patients’ follow-up operative visits 12 to 14 weeks following surgery in order to bill for a separate visit outside the normal Medicare 90 days DRG charge; (6) routinely used and billed for medically unnecessary ultrasound-guided injections; and (7) billed for certain physical therapy claims using Modifier KX so as to exceed the Medicare cap on physical therapy, even when medically unnecessary. ⁹⁹	\$4.488 million
December 28, 2016	Bay Sleep Clinic; Qualium Corporation; Amerimed Corporation; Tara Nader; Anooshiravan Mostowfipour	Bay Sleep Clinic, its related businesses, and their owners and operators agreed to pay \$2.6 million to resolve FCA allegations in a <i>qui tam</i> action styled <i>U.S. ex rel. Dresser v. Qualium Corp., et al.</i> (N.D. Cal.), in which the government intervened in 2015, that they billed Medicare (1) for sleep tests performed by technicians lacking the licenses or certifications required by Medicare payment rules and conducted at unenrolled and unapproved locations; and (2) for medical devices in violation of Medicare regulations that prohibit providers of diagnostic sleep tests from supplying medical devices and from sharing a sleep laboratory location with a DME supplier. As part of the settlement, the defendants voluntarily terminated their two existing Medicare enrollments and agreed not to re-enroll as providers or suppliers in the Medicare program for three years. ¹⁰⁰	\$2.6 million

INDIVIDUAL PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
January 6, 2016	Kurt Bauer	A former chiropractor entered into a consent decree to resolve a government lawsuit alleging that he remained involved in the management of a Medicare provider’s business despite his exclusion by HHS-OIG, in violation of the FCA. Pursuant to the decree, Bauer must pay \$30,000, consent to a renewed exclusion for the next 25 years and make bi-annual certifications to the U.S. Attorney’s Office for the next five years certifying that he is complying with his renewed exclusion. ¹⁰¹	\$30,000
May 9, 2016	John F. Kiraly, M.D.; Rena Kiraly	An oncologist and his wife, who served as the office administrator, agreed to pay \$300,000 to resolve FCA allegations that they improperly billed Medicare for certain chemotherapy drugs purchased from an unlicensed foreign pharmaceutical distributor. ¹⁰²	\$300,000

99. <https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-orthopedic-surgery-practice>.

100. <https://www.justice.gov/usao-ndca/pr/bay-sleep-clinic-and-related-entities-agree-pay-united-states-26-million-settle-false>.

101. <https://www.justice.gov/usao-mdpa/pr/united-states-reaches-agreement-former-york-county-chiropractor-civil-false-claims-act>.

102. <https://www.justice.gov/usao-edca/pr/lodi-oncologist-and-office-administrator-pay-300000-settle-false-claims-act-allegations>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
July 5, 2016	Martin E. Cutler, M.D.; Martin E. Cutler, M.D., P.C.	An ophthalmologist and his company agreed to pay \$55,000 to resolve FCA allegations that they billed Medicare for ophthalmic diagnostic imaging when there was no underlying diagnosis to justify the imaging, and for office visits where a prior claim for the same visit had been denied and the new claim was not supported by the documentation. ¹⁰³	\$55,000
July 27, 2016	Anton Fry, M.D.; CPC Associates, Inc.	A mental health practice and its psychiatrist founder agreed to pay \$36,704 to resolve FCA allegations that they billed Medicare for psychiatric services that were provided over the phone to certain Medicare beneficiaries who were not located in rural health professional shortage areas, instead of by meeting with the beneficiaries in the office and treating them in person, in violation of Medicare rules. ¹⁰⁴	\$36,704
August 17, 2016	Robert A. Scappa, D.O.	A urologist agreed to pay \$250,000 to resolve FCA allegations that he caused the submission of claims for "FISH" tests that were not medically necessary. Scappa allegedly referred FISH testing ordered by him to a laboratory owned and operated by 21st Century Oncology and was paid bonuses by the company based, in part, on the number of FISH tests he referred to the laboratory. In December 2015, 21st Century Oncology resolved related allegations in a \$19.75 million settlement. ¹⁰⁵	\$250,000
September 21, 2016	Dr. Hussein Awada	A doctor agreed to pay \$200,000 to resolve FCA allegations that he wrote prescriptions for oxycodone and other controlled medications without medical justification and billed for medically unnecessary x-rays and other invasive tests. Awada pleaded guilty in a related criminal action and was sentenced to 84 months in prison. ¹⁰⁶	\$200,000
September 22, 2016	David Margolis	A clinical social worker agreed to pay \$110,000 to resolve FCA allegations that he billed Medicare for therapy sessions that he knew never took place, either because he never actually scheduled the sessions or because his clients cancelled or missed the appointments. Margolis also agreed to be excluded from participation in federal healthcare programs for a period of five years. ¹⁰⁷	\$110,000
November 8, 2016	Dr. Duttala Obul Reddy	A district court entered judgment in favor of the government and ordered a psychiatrist to pay \$908,000 pursuant to a settlement agreement to resolve FCA allegations that he submitted bills for E/M services provided at long-term care facilities that either had not been provided or had not been provided to the extent claimed. In addition to the monetary payment, Reddy agreed to be excluded from participation in federal healthcare programs for 10 years. ¹⁰⁸	\$908,000

103. <https://www.justice.gov/usao-ma/pr/north-shore-ophthalmologist-agrees-pay-55000-resolve-false-medicare-billing-allegations>.

104. <https://www.justice.gov/usao-ct/pr/danbury-physician-and-mental-health-practice-pay-36000-settle-false-claims-act>.

105. <https://www.justice.gov/usao-mdfl/pr/fort-myers-urologist-agrees-pay-250000-ordering-unnecessary-medical-tests>.

106. <https://www.justice.gov/usao-edmi/pr/united-states-settles-health-care-fraud-action-involving-doctor-who-prescribed>.

107. <https://www.justice.gov/usao-ma/pr/winchester-therapist-agrees-pay-110000-resolve-false-medicare-billing-allegations>.

108. <https://www.justice.gov/usao-cdil/pr/springfield-psychiatrist-ordered-pay-908000-civil-settlement>.

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
November 23, 2016	Anthony Clavo, M.D.	A pain management physician agreed to enter into a consent judgment for \$430,000 to resolve FCA allegations that he billed federal healthcare programs for services that were medically unnecessary or where there was insufficient information to determine the amount due to the provider. ¹⁰⁹	\$430,000
December 13, 2016	Lynn E. Madsen, M.D.	A physician agreed to pay \$76,000 to resolve FCA allegations that she billed Medicare and Medicaid for trigger point injections consisting solely of saline or saline-based anthroposopic injectates that were devoid of any approved therapeutic agent and not considered reasonable and medically necessary under applicable Medicare and Medicaid laws, regulations and program limitations. ¹¹⁰	\$76,000

MISCELLANEOUS/NON-PROVIDERS

DATE	ENTITY	FCA ALLEGATIONS	SETTLEMENT AMOUNT
May 5, 2016	City of New York	The City of New York agreed to pay \$4.3 million to resolve FCA allegations involving the New York City Fire Department's receipt of Medicare reimbursements for claims for emergency ambulance services that did not meet Medicare's medical necessity requirement, which the City of New York had identified but did not take steps to inform Medicare of for more than four years. The City of New York voluntarily disclosed this matter to the government. ¹¹¹	\$4.3 million
June 27, 2016	Irving Holdings, Inc.; JetTaxi, Inc.; Dallas Taxi, LLC; US Cab, LLC; Terminal Taxi Corporation of Irving; Classic Shuttle Acquisition Corporation, Inc.; Dallas Car Leasing, LLC; Jackie Bewley; Jeffrey Finkel; Elizabeth George	Three individual executives and seven taxicab companies, who provide transportation to Medicare and Medicaid patients if they cannot travel or have no access to transportation, agreed to pay a total of \$1.125 million to resolve FCA allegations that they misrepresented their compliance with regulations governing Medicaid transportation services, resulting in false claims being submitted to Texas Medicaid and CMS. ¹¹²	\$1.125 million
July 14, 2016	The Trustees of Columbia University in the City of New York	Columbia University agreed to pay \$9.5 million to resolve FCA allegations that it (1) impermissibly applied its higher "on-campus" indirect cost rate when seeking federal reimbursement for 423 National Institutes of Health (NIH) grants where the research was primarily performed at off-campus facilities owned and operated by the State of New York and New York City; and (2) failed to disclose to NIH that it did not own or operate these facilities and did not pay for use of the space for most of the relevant period. ¹¹³	\$9.5 million

109. <https://www.justice.gov/usao-ndga/pr/pain-management-physician-resolves-false-claims-act-allegations>.

110. <https://www.justice.gov/usao-vt/pr/vermont-physician-pays-76000-united-states-resolve-allegations-false-claims-act>.

111. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-43-million-settlement-false-claims-act-action-based-new>.

112. <https://www.justice.gov/usao-edtx/pr/north-texas-companies-and-individuals-pay-1125-million-settle-medicare-allegations>.

113. <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-95-million-settlement-columbia-university-improperly>.

ABOUT BASS, BERRY & SIMS PLC



The Bass, Berry & Sims Healthcare Fraud Task Force represents healthcare providers in connection with fraud and abuse matters, including responding to governmental inquiries by the U.S. DOJ and U.S. Attorneys' Offices, the Office of Inspector General of the U.S. Department of Health and Human Services, federal program safeguard contractors, and various states' Attorneys General offices. We have a track record of successfully representing providers in related FCA litigation, including obtaining declinations and dismissals in numerous FCA *qui tam* cases. We routinely counsel healthcare providers on implementing state-of-the-art compliance programs and assist clients in navigating self-disclosure and other compliance-related projects.

The firm's healthcare fraud and abuse practice is led by former members of the U.S. DOJ and a number of former Assistant U.S. Attorneys with significant experience handling healthcare fraud matters. Our attorneys are frequent speakers on healthcare fraud and abuse topics and two of our members serve as Adjunct Professors of Law at Vanderbilt Law School teaching Healthcare Fraud and Abuse. For more information, please visit our website at <http://www.bassberry.com/healthcare-fraud>.



J. Taylor Chenery
Member
615.742.7924
tchenery@bassberry.com



Robert E. Cooper, Jr.
Member
615.742.7768
rcooper@bassberry.com



Matthew M. Curley
Member
615.742.7790
mcurley@bassberry.com



Wallace W. Dietz
Member
615.742.6276
wdietz@bassberry.com



Anna M. Grizzle
Member
615.742.7732
agrizzle@bassberry.com



John E. Kelly
Member
202.827.2953
jkelly@bassberry.com



Eli J. Richardson
Member
615.742.7825
erichardson@bassberry.com



Lisa S. Rivera
Member
615.742.7707
lrivera@bassberry.com



Brian D. Roark
Member
615.742.7753
broark@bassberry.com



Glenn B. Rose
Member
615.742.6273
grose@bassberry.com



Danielle M. Sloane
Member
615.742.7763
dsloane@bassberry.com

Taylor Chenery focuses his practice on government compliance and investigations and related FCA litigation, focusing on issues of healthcare fraud and abuse. Taylor represents healthcare providers in government inquiries and investigations by the HHS-OIG, U.S. Attorneys' Offices and the DOJ.

Bob Cooper advises clients on matters related to compliance and enforcement issues and assists clients in responding to internal government investigations. Bob rejoined the firm in 2015 after 12 years of public service, serving as legal counsel to Tennessee Governor Phil Bredesen from 2003-2006 and Attorney General from 2006-2014. While Tennessee Attorney General, Bob formed a division within the Attorney General's Office devoted to pursuing provider Medicaid fraud and recovered more than \$150 million for the state.

Matthew Curley represents healthcare providers in connection with civil and criminal investigations by federal and state regulators and in related FCA litigation. Matt previously was Assistant U.S. Attorney with the U.S. Attorney's Office for the Middle District of Tennessee, where he served as Civil Chief and coordinated enforcement efforts arising under the FCA. He is an adjunct professor at Vanderbilt Law School, teaching Healthcare Fraud and Abuse.

Wallace Dietz is chair of the firm's Compliance & Government Investigations Practice Group. His practice includes representing healthcare companies facing whistleblower lawsuits under the FCA or other regulatory violations and conducting internal and government investigations. Wally has notable successes negotiating with the DOJ, FTC, various state regulators and other governmental agencies.

Anna Grizzle focuses her practice exclusively on helping healthcare clients address enforcement and compliance issues and in responding to legal and regulatory violations. Anna advises on the reporting and repayment of overpayments and in responding to payor audits and has advised a number of healthcare clients in self-disclosures, including disclosures made through the physician self-referral (Stark Law) and HHS-OIG disclosure protocols.

John Kelly is the Managing Partner of the firm's Washington, D.C. office and is an experienced trial lawyer who represents healthcare providers, life sciences companies and individuals in investigations and enforcement actions concerning the FCA, AKS, Stark Law and the FDCA. John previously served as a prosecutor with DOJ where he held a number of leadership positions, including Assistant Chief for Healthcare Fraud, Criminal Division, Fraud Section; Lead Prosecutor, Medicare Fraud Strike Force; and Chief of Staff and Deputy Director of EOUSA.

Eli Richardson helps businesses respond to government investigations involving alleged white-collar crime or quasi-criminal civil violations. He conducts internal investigations, advises on compliance policies, provides compliance training and helps clients in self-disclosure to government authorities. Eli previously held positions with the DOJ, including serving as Criminal Chief at the U.S. Attorney's Office and with the FBI.

Lisa Rivera focuses her practice on advising healthcare providers on matters related to civil and criminal healthcare fraud and abuse, as well as government investigations and enforcement. Lisa previously served for 13 years as an Assistant U.S. Attorney, with 10 years in the U.S. Attorney's Office for the Middle District of Tennessee, where she was Civil and Criminal Healthcare Fraud Coordinator and responsible for coordination of all criminal and civil healthcare fraud investigations.

Brian Roark leads the firm's Healthcare Fraud Task Force and concentrates his practice on representing healthcare clients in responding to governmental investigations and defending FCA lawsuits. He has successfully litigated and resolved numerous healthcare fraud matters and frequently represents clients in connection with Medicare audits and overpayment disputes. Brian is an adjunct professor at Vanderbilt Law School, teaching Healthcare Fraud and Abuse.

Glenn Rose represents clients in complex business disputes and healthcare litigation, including defending FCA lawsuits, conducting internal investigations and assisting clients with risk management issues.

Danielle Sloane helps life science and healthcare clients navigate federal and state healthcare laws and regulations. She frequently advises clients on compliance, fraud and abuse, and operational matters, including self-disclosures, voluntary repayments, overpayments, compliance plans and audits, and internal investigations.

Angela Bergman represents clients in investigations and litigation related to compliance and alleged FCA violations, including hospital billing practices, medical necessity issues, and other fraud and abuse matters.

John Eason represents clients in government enforcement actions, investigations, and related litigation, particularly involving the FCA. He has represented companies and individuals in responding to inquiries and investigations by the DOJ, HHS-OIG and other federal and state agencies regarding healthcare and procurement fraud issues.

Lindsey Fetzer focuses her practice on white collar and corporate compliance matters, including healthcare fraud and abuse issues. Lindsey has represented clients in foreign and domestic matters involving DOJ, the SEC, and other primary enforcement agencies.

Lauren Gaffney represents healthcare clients concerning regulatory compliance and healthcare fraud matters, and has advised clients concerning self-disclosures and in connection with responding to audits and appeals by government contractors.

Jeff Gibson defends individuals and companies facing white collar criminal charges, quasi-criminal civil claims and compliance violations. He leads internal investigations, addresses compliance issues and provides crisis management services.

Meri Gordon represents clients in matters related to compliance issues under the FCA, Stark Law and AKS. She also helps clients respond to government investigations by HHS-OIG, U.S. Attorneys' Offices and the DOJ.

Kaitlin Harvie represents healthcare providers in connection with internal investigations and related proceedings, focusing on issues of healthcare fraud and abuse. She has significant experience with conducting anti-corruption investigations, compliance reviews and due diligence efforts.

Kate Hunter concentrates her practice on investigations and litigation related to inquiries involving alleged violations of the FCA, the Foreign Corrupt Practices Act (FCPA), various securities laws and other federal statutes.

Brian Irving represents healthcare providers in litigation matters brought under the FCA and helps them respond to government inquiries brought by the HHS-OIG, U.S. Attorneys' Offices and the DOJ.

John Lawrence represents healthcare clients on various federal and state compliance issues, including the FCA, Stark Law and AKS. He works with clients in defense of allegations of healthcare fraud and abuse.

Katherine Linsey focuses her practice on corporate compliance matters, including those related to healthcare fraud and abuse, and adherence to federal anti-corruption laws such as the FCA and the FCPA.

Robert Platt represents companies and individuals in government and internal investigations matters involving DOJ, HHS-OIG, the SEC and other federal enforcement and regulatory agencies.

Molly Ruberg represents healthcare providers in connection with government enforcement actions, investigations and related litigation. She routinely counsels clients related to compliance and defense of FCA violations, self-disclosures and responding to governmental inquiries.

Julia Tamulis advises healthcare providers on Medicare appeals and hearings related to reimbursement denials and provides guidance on governmental investigations of healthcare providers concerning potential fraud and abuse matters. Julia previously was as an attorney-advisor for HHS's Departmental Appeals Board.

BASS BERRY  SIMS
CENTERED TO DELIVER.

NASHVILLE KNOXVILLE MEMPHIS WASHINGTON DC bassberry.com